

Clinical trials of omega-3 fatty acids for cardiovascular prevention in all type of patients

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1 omega-3 Fatty acids

Trial	Treatments	Patients	Trials design and methods
diet vs control			
Burr (DART 2) , 2003 n=1571/1543 follow-up: 36-108 months	dietary advice (to eat more oily fish) versus No such dietary advice or capsules	men being treated for angina	Parallel groups open UK
Burr (DART) , 1989 n=1015/1018 follow-up: 24 months	dietary advice (to eat more oily fish) versus No such dietary advice or capsulesish)ag	post-MI	Parallel groups open UK
Mate-Jimenez , 1991 n=19/19 follow-up: 24months	diet advice versus no advice	people with inactive Crohns disease	Parallel groups open with blind assessment Spain
fish oil vs control			
Bemelmans , 2002 n=51/52 follow-up: 24 months	a-lin rich margarine (80% fat of which 15% was a-lin) versus linoleic rich margarine (80% fat of which 0.3% was a-lin), identical in taste and packaging	patients with multiple cardiovascular risk factors (10 yr IHD risk 20%)	Parallel groups double-blind the Netherlands
Brox , 2001 n=40/40 follow-up:	seal oil - 15 ml/d (2.6g EPA + DHA) versus no supplement	dyslipidaemia	open with blind assessment
Franzen , 1993 n=15/15 follow-up: 12 months	fish oil capsules, 9g/d (1.8g EPA + 1.4g DHA daily) versus olive oil capsules	people with angiographically determined CHDg	Parallel groups double-blind
Katan , 1997 n=44/14 follow-up: 12 months	Fish oil capsules, all took 9 per day (1.1g omega-3 fats low dose, 2.2g medium dose, 3.3g high dose per day) versus 9 olive and palm oil capsules (0g omega-3 fats per day)j	healthy monks	Parallel groups NA The Netherland
Malaguarnera , 1999 n=26/26 follow-up: 6 months	EPA + DHA daily (3g/d EPA + DHA) plus IFNa subcutaneously versus IFNa subcutaneously only	chronic hepatitis with ALT =2x normal limit for =12 mo	Parallel groups open Italy

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Trial	Treatments	Patients	Trials design and methods
Shimizu , 1995 n=29/16 follow-up: 12 months	EPA-ethyl capsules 3/d (0.9g/d EPA) versus no treatment	people with non-insulin dependant diabetes	Parallel groups open Japan
Terano , 1999 n=10/10 follow-up: 12 months	DHA capsules, 6/d (4.3g/d DHA) versus no treatment	dementia of CVD	Parallel groups open with blind assessment japan
MaxEPA vs control			
Bellamy , 1992 n=60/60 follow-up: 7 months	MaxEPA capsules (3g/d EPA + DHA) versus no treatment	people referred for coronary angioplasty	Parallel groups NA UK
Dehmer , 1998 n=46/44 follow-up: 6 months	MaxEPA capsules, 18/d (5.4g EPA + DHA daily) versus no treatment	men undergoing coronary angioplasty imag	open US
Kaul , 1992 n=58/49 follow-up: 6 months	MaxEPA capsules, 10/d (3g/d EPA + DHA) versus no treatment	people undergoing angioplasty	Parallel groups open India
Omacor vs control			
Eritsland , 1996 n=317/293 follow-up: 12 months	Omacor capsules, 4/d (3.3g EPA + DHA daily) versus no treatment	people admitted for coronary bypass grafting	Parallel groups open Norway
GISSI-P , 1999 n=5665/5668 follow-up: median 40 months	Omacor gelatine capsules, 1/d (0.9g/d EPA + DHA daily) versus no treatment	people with recent myocardial infarction	Parallel groups open Italy
omega-3 Fatty acids vs control			
OMEGA , 2009 [NCT00251134] n=1940/1911 follow-up: 1 year	omega-3 fatty acids 1g daily (and standard medical therapy) versus standard medical therapy alone	Patients within 3-14 days after a non-ST-elevation myocardial infarction (NSTEMI) or ST-elevation myocardial infarction (STEMI)	Parallel groups open Germany
Promega vs control			
Milner , 1989 n=100/100 follow-up: 6 months	Promega 9 capsules/d (4.5g EPA + DHA) versus no treatment	people about to undergo angioplasty	Parallel groups open with blind assessment US
alpha-linolenic acid vs placebo			

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Trial	Treatments	Patients	Trials design and methods
ALPHA OMEGA (ALA) , 2010 [NCT00127452] n=2409/2428 follow-up: 40 months	margarine supplemented with plant-derived alpha-linolenic acid (with a targeted additional daily intake of 2 g of ALA) versus placebo	men and women with a history of myocardial infarction	Factorial plan double-blind the Netherlands
Natvig , 1968 n=6716/6690 follow-up: 12 months	linseed oil, 10 ml /d (55% a-linolenic acid) versus placebo (sunflower oil, 10 ml/d (1.4% a-linolenic acid))	working men, though a few had had a previous MI or angina	Parallel groups double-blind Norway
Efamol marine vs placebo			
Veale , 1994 n=19/19 follow-up: 9 months	Efamol marine capsules, 12/d (0.4g/d EPA + DHA plus 0.5g/d gamma-linoleic acid (notomega-3))TP versus placebo (capsules containing liquid paraffin and vitamin E, 12/d, appeared identical)	people with chronic stable plaque psoriasis and inflammatory arthritis	Parallel groups double blind UK
Esapent vs placebo			
Maresta , 2002 n=169/170 follow-up: 7 months	Esapent capsules, 6/d for 2 mo, then 3/d (5.1g/d EPA + DHA initially, later 2.6g/d) versus placebo (identical olive oil capsules, 6/d for 2 mo, then 3/d)	undergoing planned PTCAB	Parallel groups double-blind Italy
Sirtori , 1998 n=470/465 follow-up: 6 months	Esapent fish oil capsules 3/d for first 2 mo, 2/d after that (2.6g/dEPA + DHA initially, then 1.8g/d) versus placebo (olive oil capsules 3/d for first 2 mo, 2/d after that)	people with raised triglycerides plus glucose intolerance, non-insulindependent diabetes or hypertension	Parallel groups double blind Italy
Eskisol vs placebo			
Rossing , 1996 n=18/18 follow-up: 12 months	Eskisol fish oil emulsion 21 ml/d (4.6g EPA +DHA) versus placebo (olive oil emulsion 21 ml/d)	people with insulin dependant diabetes, diabetic nephropathy and normalBP	Parallel groups double blind Denmark
fish oil vs placebo			
Almallah , 1998 n=18/18 follow-up: 6 months	fish oil extract, 15 ml/d (5.6g EPA + DHA) versus placebo (sunflower oil, 15 ml/d)	people with distal procto-collitis (ulcerative colitis)	Parallel groups single blind and outcome ass. UK
Borchgrevink , 1966 n=100/100 follow-up: mean 10 months (range 3-16 mo)	linseed oil 10 ml/d initially, later raised to 20 or 30 ml/d (4.5g/d a-lin, later 9 or 13.5 g/d) versus placebo (corn oil, 10 ml/d initially, later raised to 20 or 30 ml/d)	men with impending or recent myocardial infarction	Parallel groups double-blind Norway

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Trial	Treatments	Patients	Trials design and methods
Dry , 1991 n=6/6 follow-up: 12 months	Liparmonyl (1g/d EPA + DHA) versus placebo	people with asthma	Parallel groups double blind France
Geusens , 1994 n=60/30 follow-up: 12 months	high and ow dose fish oil capsules versus placebo (olive oil capsules, 6/d)	people with active rheumatoid arthritis on NSAIDs or DMARDs	Parallel groups double blind Belgium
Leaf , 1994 n=275/276 follow-up: 6 months	fish oil concentrate capsules 10x1 g/d (6.9g/d EPA + DHA) versus placebo (corn oil capsules 10x1 g/d with 0.4% fish oil to maintain blinding (0.003g/d EPA + DHA))	people undergoing angioplasty	Parallel groups double blind US
Loeschke , 1996 n=31/33 follow-up: 24 months	fish oil capsules 6x1 g/d (5.1g/d omega-3 fats), with orange flavour versus placebo (maize oil capsules 6x1 g/d with orange flavour)	people with ulcerative colitis, in remission	Parallel groups double-blind Germany
Lorenz-Meyer , 1996 n=70/65 follow-up: 12 months	ethyl ester fish oil concentrate capsules 6x1 g daily (5.1g/d EPA + DHA) versus placebo (corn oil capsules 6x1 g daily)	people with Crohns disease in remission	Parallel groups double blind
Sacks (TOHP 1) , 1994 [NCT00000528] n=NA follow-up:	fish oil versus placebo	double blind	double-blind
von Schacky , 1999 n=112/111 follow-up: 24 months	concentrated fish oil capsules, 6/d for first 3 mo, 3/d for rest of study (4g/d EPA +DHA + DPA+ a-lin for first 3 mo, then 2g/d) versus placebo (capsules containing fat which replicated the fat composition of the average European diet, 6/d forfirst 3 mo, 3/d for rest of study, opaque soft gelatine capsules identical to fish capsules)	people with angiographically proven coronary artery disease	Parallel groups double blind Germany
HiEPA vs placebo			
Hawthorne , 1992 n=49/47 follow-up: 12 months	HiEPA oil, 10 ml x 2/d (5.6g/d EPA + DHA) versus placebo (olive oil, 10 ml x 2/d (0g/d EPA + DHA))	people with ulcerative colitis	Parallel groups double blind UK
MaxEPA vs placebo			
Bairati , 1992 n=107/98 follow-up: 7 months	MaxEPA, 15 capsules/d (4.5g EPA + DHA) versus placebo (olive oil, 15 capsules/d)	patients undergoing planned angioplasty	Parallel groups double blind Canada

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Trial	Treatments	Patients	Trials design and methods
Greenfield , 1993 n=16/8 follow-up: 6 months	MaxEPA capsules, 12/d for first month, then 6/d (3.7g/d initially, then 1.9g EPA + DHA daily), all with peppermint oil to disguise taste versus placebo (olive oil capsules, 12/d for first month, then 6/d. Looked like MaxEPA and had added peppermint oil)	people with stable ulcerative colitis	Parallel groups double blind UK
Lau , 1993 n=32/32 follow-up: 12 months	MaxEPA 10x 1g capsules daily (2.8g/d EPA + DHA) versus placebo (air-filled capsules, 10/d)	people with rheumatoid arthritis	Parallel groups double blind UK
Lau , 1995 n=25/20 follow-up: 6 months	MaxEPA 10x 1g capsules daily (2.8g/d EPA + DHA) versus placebo (air-filled capsules, 10/d)	people with rheumatoid arthritis	Parallel groups double blind Hong Kong
Nye , 1990 n=36/37 follow-up: 12 months	MaxEPA capsules 12/d (2.2g EPA) versus placebo (olive oil capsules, 12/d, identical to MaxEPA)	people undergoing angioplasty	Parallel groups double blind New Zealand
Singh , 1997 n=122/118 follow-up: 12 months	MaxEPA fish oil capsules 6/d (1.8g EPA + DHA) versus placebo (aluminium hydroxide 100 mg/d)	people with suspected acute MI	Parallel groups double blind India
Skoldstam , 1992 n=23/23 follow-up: 6 months	MaxEPA fish oil capsules 10/d (3.0g/d EPA + DHA) versus placebo (vegetable oil capsules 10/d)	people with rheumatoid arthritis	Parallel groups double blind Sweden
Thien , 1993 n=21/16 follow-up: 6 months	MaxEPA capsules, 18/d (5.4g/d EPA + DHA) versus placebo (olive oil capsules 18/d)	hayfever and asthma	Parallel groups double blind Australia
Omacor vs placebo			
Johansen , 1999 n=250/250 follow-up: 6.5 months	Omacor capsules, 6/d (5g EPA + DHA daily) versus placebo (corn oil capsules, 6/d)	people about to undergo elective coronary angioplasty	Parallel groups double blind Norway
Nilsen , 2001 n=150/150 follow-up: 24 months	Omacor capsules 4/d (3.5g EPA + DHA) versus placebo (corn oil capsules, 4/d)	people with acute myocardial infarction 4-8 days ago	Parallel groups double-blind Norway
omega-3 fatty acids vs placebo			

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Trial	Treatments	Patients	Trials design and methods
ALPHA OMEGA (EPA DHA) , 2010 [NCT00127452] n=2404/2433 follow-up: 40 months	400 mg per day supplement of the fish oil fatty acids EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) via enriched margarines versus placebo	men and women with a history of myocardial infarction	Factorial plan double-blind the Netherlands
Risk and Prevention Study , 2013 [NCT00317707.] n=6244/6269 follow-up: 5 year (median)	n-3 fatty acids (1 g daily) versus placebo (olive oil)	men and women with multiple cardiovascular risk factors or atherosclerotic vascular disease but not myocardial infarction	double-blind
GISSI HF fatty acid , 2008 [NCT00336336.] n=3494/3481 follow-up: 3.9y median (IQR 3-4.4)	n-3 polyunsaturated fatty acids (PUFA) 1 g daily versus placebo	Patients with NYHA classes II to IV heart failure, whatever the cause and the LVEF and already receiving optimized recommended therapy with no clear indication or contraindication to cholesterol-lowering therapy	double blind Italy
n3-PUFA-HF ongoing [NCT00149409] n=NA follow-up:	Omega-3-Polyunsaturated Fatty-Acids (EPH/DHA 1:1.2) versus placebo	Patients With Severe Chronic Heart Failure	Parallel groups double blind
Pikazol vs placebo			
Bonnema , 1995 n=14/14 follow-up: 24 months	Pikazol fish oil capsules, 6x1 g/d (3.3g EPA + DHA) versus placebo (olive oil capsules, 6x1 g/d)	people with insulin treated diabetes and microalbuminureakK	Parallel groups double-blind Denmark
Promega vs placebo			
Connor , 1993 n=8/8 follow-up: 6 months	Promega oil, 15g/d (6g/d EPA + DHA) versus placebo (Olive oil, 15g/d)	people with non-insulin dependant diabetes and hypertiglyceridaemia	Parallel groups double-blind US
Sacks (HARP) , 1995 n=41/39 follow-up: 29 months	Promega capsules 12x1 g/d (6.0g EPA + DHA + DPA) versus placebo (olive oil capsules, 12x1 g/d)	people with angiographically documented CHD DPA)	Parallel groups double-blind US
PurEPA vs placebo			
Belluzzi , 1996 n=39/39 follow-up: 12 months	PurEPA 3 enteric coated capsules/d (0.9g EPA + DHA) versus placebo (Mixed TG 3 enteric coated capsules)	established Crohns disease, in remission	Parallel groups double-blind Italy
Super EPA vs placebo			

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Trial	Treatments	Patients	Trials design and methods
Reis , 1991 n=146/72 follow-up: 6 months	Super EPA capsules 12x1 g/d (7.0g EPA + DHA + a-lin) ORPromega capsules 12x1 g/d (6.0g EPA + DHA + a-lin) versus placebo (olive oil capsules, 12x1 g/d)	people undergoing angioplasty	Parallel groups double blind US

References

Burr (DART 2), 2003:

Ness AR, Gallacher JE, Bennett PD, Gunnell DJ, Rogers PJ, Kessler D, Burr ML Advice to eat fish and mood: a randomised controlled trial in men with angina. *Nutr Neurosci* 2003 Feb;6:63-5 [[12608739](#)]

Burr (DART), 1989:

Burr ML, Fehily AM, Gilbert JF, Rogers S, Holliday RM, Sweetnam PM, Elwood PC, Deadman NM Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). *Lancet* 1989 Sep 30;2:757-61 [[2571009](#)]

Ness AR, Whitley E, Burr ML, Elwood PC, Smith GD, Ebrahim S The long-term effect of advice to eat more fish on blood pressure in men with coronary disease: results from the diet and reinfarction trial. *J Hum Hypertens* 1999 Nov;13:729-33 [[10578215](#)]

Mate-Jimenez, 1991:

Bemelmans, 2002:

Bemelmans WJ, Broer J, Feskens EJ, Smit AJ, Muskiet FA, Lefrandt JD, Bom VJ, May JF, Meyboom-de Jong B Effect of an increased intake of alpha-linolenic acid and group nutritional education on cardiovascular risk factors: the Mediterranean Alpha-linolenic Enriched Groningen Dietary Intervention (MARGARIN) study. *Am J Clin Nutr* 2002 Feb;75:221-7 [[11815311](#)]

Bemelmans WJ, Broer J, de Vries JH, Hulshof KF, May JF, Meyboom-De Jong B Impact of Mediterranean diet education versus posted leaflet on dietary habits and serum cholesterol in a high risk population for cardiovascular disease. *Public Health Nutr* 2000 Sep;3:273-83 [[10979147](#)]

Brox, 2001:

Brox J, Olaussen K, Osterud B, Elvevoll EO, Bjornstad E, Brattebog G, Iversen H A long-term seal- and cod-liver-oil supplementation in hypercholesterolemic subjects. *Lipids* 2001 Jan;36:7-13 [[11214732](#)]

Franzen, 1993:

Franzen D, Geisel J, Hpp HW, Oette K, Hilger HH [Long-term effects of low dosage fish oil on serum lipids and lipoproteins] *Med Klin (Munich)* 1993;88:134-8 [[8474402](#)]

Katan, 1997:

Katan MB, Deslypere JP, van Birgelen AP, Penders M, Zegwaard M Kinetics of the incorporation of dietary fatty acids into serum cholesteryl esters, erythrocyte membranes, and adipose tissue: an 18-month controlled study. *J Lipid Res* 1997 Oct;38:2012-22 [[9374124](#)]

Blok WL, Deslypere JP, Demacker PN, van der Ven-Jongekrijg J, Hectors MP, van der Meer JW, Katan MB Pro- and anti-inflammatory cytokines in healthy volunteers fed various doses of fish oil for 1 year. *Eur J Clin Invest* 1997 Dec;27:1003-8 [[9466128](#)]

Malaguarnera, 1999:

Malaguarnera M, Restuccia N, Fazio ID, Panebianco MP, Gulizia G, Giugno I Fish oil treatment of interferon-alpha-induced dyslipidaemia: study in patients with chronic hepatitis C. *BioDrugs* 1999;11:285-91 [[18031138](#)]

Shimizu, 1995:

Shimizu H, Ohtani K, Tanaka Y, Sato N, Mori M, Shimomura Y Long-term effect of eicosapentaenoic acid ethyl (EPA-E) on albuminuria of non-insulin dependent diabetic patients. *Diabetes Res Clin Pract* 1995;28:35-40 [[7587910](#)]

Terano, 1999:

Terano T, Fujishiro S, Ban T, Yamamoto K, Tanaka T, Noguchi Y, Tamura Y, Yazawa K, Hirayama T Docosahexaenoic acid supplementation improves the moderately severe dementia from thrombotic cerebrovascular diseases. *Lipids* 1999;34 Suppl:S345-6 [[10419198](#)]

Bellamy, 1992:

Bellamy CM, Schofield PM, Faragher EB, Ramsdale DR Can supplementation of diet with omega-3 polyunsaturated fatty acids reduce coronary angioplasty restenosis rate? *Eur Heart J* 1992 Dec;13:1626-31 [[1289091](#)]

Dehmer, 1998:

Dehmer GJ, Popma JJ, van den Berg EK, Eichhorn EJ, Prewitt JB, Campbell WB, Jennings L, Willerson JT, Schmitz JM Reduction in the rate of early restenosis after coronary angioplasty by a diet supplemented with n-3 fatty acids. *N Engl J Med* 1988 Sep 22;319:733-40 [[2842680](#)]

Kaul, 1992:

Kaul U, Sanghvi S, Bahl VK, Dev V, Wasir HS Fish oil supplements for prevention of restenosis after coronary angioplasty. *Int J Cardiol* 1992 Apr;35:87-93 [[1563884](#)]

Eritsland, 1996:

Eritsland J, Arnesen H, Gronseth K, Fjeld NB, Abdelnoor M Effect of dietary supplementation with n-3 fatty acids on coronary artery bypass graft patency. *Am J Cardiol* 1996 Jan 1;77:31-6 [[8540453](#)]

Eritsland J, Arnesen H, Seljeflot I, Hostmark AT Long-term metabolic effects of n-3 polyunsaturated fatty acids in patients with coronary artery disease. *Am J Clin Nutr* 1995 Apr;61:831-6 [[7702027](#)]

GISSI-P, 1999:

Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial. Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico. *Lancet* 1999 Aug 7;354:447-55 [[10465168](#)]

Marchioli R, Barzi F, Bomba E, Chieffo C, Di Gregorio D, Di Mascio R, Franzosi MG, Geraci E, Levantesi G, Maggioni AP, Mantini L, Marfisi RM, Mastrogiuseppe G, Mininni N, Nicolosi GL, Santini M, Schweiger C, Tavazzi L, Tognoni G, Tucci C, Valagussa F Early protection against sudden death by n-3 polyunsaturated fatty acids after myocardial infarction: time-course analysis of the results of the Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico (GISSI)-Prevenzione. *Circulation* 2002 Apr 23;105:1897-903 [[11997274](#)]

OMEGA, 2009:

Senges Randomized Trial of Omega-3 Fatty Acids on Top of Modern Therapy After Acute Myocardial Infarction: The OMEGA Trial ACC.09/i2, Orlando, FL, March 2009 [[0](#)]

Rauch B, Schiele R, Schneider S, Diller F, Victor N, Gohlke H, Gottwik M, Steinbeck G, Del Castillo U, Sack R, Worth H, Katus H, Spitzer W, Sabin G, Seneges J OMEGA, a randomized, placebo-controlled trial to test the effect of highly purified omega-3 fatty acids on top of modern guideline-adjusted therapy after myocardial infarction. *Circulation* 2010;122:2152-9 [[21060071](#)] [10.1161/CIRCULATIONAHA.110.948562](#)

Milner, 1989:

Milner MR, Gallino RA, Leffingwell A, Pichard AD, Brooks-Robinson S, Rosenberg J, Little T, Lindsay J Jr Usefulness of fish oil supplements in preventing clinical evidence of restenosis after percutaneous transluminal coronary angioplasty. *Am J Cardiol* 1989 Aug 1;64:294-9 [[2526993](#)]

ALPHA OMEGA (ALA), 2010:

Kromhout D, Giltay EJ, Geleijnse JM n-3 Fatty Acids and Cardiovascular Events after Myocardial Infarction. *N Engl J Med* 2010 Nov 18;363:2015-2026 [[20929341](#)] [10.1056/NEJMoa1003603](#)

Natvig, 1968:**Veale, 1994:**

Veale DJ, Torley HI, Richards IM, O'Dowd A, Fitzsimons C, Belch JJ, Sturrock RD A double-blind placebo controlled trial of Efamol Marine on skin and joint symptoms of psoriatic arthritis. *Br J Rheumatol* 1994;33:954-8 [[7921757](#)]

Maresta, 2002:

Skali H, Solomon SD, Pfeffer MA Are we asking too much of our trials? *Am Heart J* 2002 Jan;143:1-3 [[11773904](#)]

Sirtori, 1998:

Sirtori CR, Crepaldi G, Manzato E, Mancini M, Rivellese A, Paoletti R, Pazzucconi F, Pamparana F, Stragliotto E One-year treatment with ethyl esters of n-3 fatty acids in patients with hypertriglyceridemia and glucose intolerance: reduced triglyceridemia, total cholesterol and increased HDL-C without glyceimic alterations. *Atherosclerosis* 1998;137:419-27 [[9622285](#)]

Rossing, 1996:

Rossing P, Hansen BV, Nielsen FS, Myrup B, Hlmer G, Parving HH Fish oil in diabetic nephropathy. *Diabetes Care* 1996;19:1214-9 [8908382]

Almallah, 1998:

Almallah YZ, Richardson S, O'Hanrahan T, Mowat NA, Brunt PW, Sinclair TS, Ewen S, Heys SD, Eremin O Distal procto-colitis, natural cytotoxicity, and essential fatty acids. *Am J Gastroenterol* 1998 May;93:804-9 [9625132]

Borchgrevink, 1966:

Borchgrevink CF, Skaga E, Berg KJ, Skjaeggestad O Absence of prophylactic effect of linolenic acid in patients with coronary heart-disease. *Lancet* 1966 Jul 23;2:187-9 [4161161]

Dry, 1991:

Dry J, Vincent D Effect of a fish oil diet on asthma: results of a 1-year double-blind study. *Int Arch Allergy Appl Immunol* 1991;95:156-7 [1834587]

Geusens, 1994:

Geusens P, Wouters C, Nijs J, Jiang Y, Dequeker J Long-term effect of omega-3 fatty acid supplementation in active rheumatoid arthritis. A 12-month, double-blind, controlled study. *Arthritis Rheum* 1994 Jun;37:824-9 [8003055]

Leaf, 1994:

Leaf A, Jorgensen MB, Jacobs AK, Cote G, Schoenfeld DA, Scheer J, Weiner BH, Slack JD, Kellett MA, Raizner AE Do fish oils prevent restenosis after coronary angioplasty? *Circulation* 1994 Nov;90:2248-57 [7955181]

Mehta VY, Jorgensen MB, Raizner AE, Wolde-Tsadik G, Mahrer PR, Mansukhani P Spontaneous regression of restenosis: an angiographic study. *J Am Coll Cardiol* 1995 Sep;26:696-702 [7642861]

Loeschke, 1996:

Loeschke K, Ueberschaer B, Pietsch A, Gruber E, Ewe K, Wiebecke B, Heldwein W, Lorenz R n-3 fatty acids only delay early relapse of ulcerative colitis in remission. *Dig Dis Sci* 1996 Oct;41:2087-94 [8888725]

Lorenz-Meyer, 1996:

Lorenz-Meyer H, Bauer P, Nicolay C, Schulz B, Purrmann J, Fleig WE, Scheurlen C, Koop I, Pudel V, Carr L Omega-3 fatty acids and low carbohydrate diet for maintenance of remission in Crohn's disease. A randomized controlled multicenter trial. Study Group Members (German Crohn's Disease Study Group). *Scand J Gastroenterol* 1996 Aug;31:778-85 [8858747]

Sacks (TOHP 1), 1994:

The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels. Results of the Trials of Hypertension Prevention, Phase I. *JAMA* 1992 Mar 4;267:1213-20 [1586398]

von Schacky, 1999:

von Schacky C, Angerer P, Kothny W, Theisen K, Mudra H The effect of dietary omega-3 fatty acids on coronary atherosclerosis. A randomized, double-blind, placebo-controlled trial. *Ann Intern Med* 1999;130:554-62 [10189324]

Hawthorne, 1992:

Hawthorne AB, Daneshmend TK, Hawkey CJ, Belluzzi A, Everitt SJ, Holmes GK, Malkinson C, Shaheen MZ, Willars JE Treatment of ulcerative colitis with fish oil supplementation: a prospective 12 month randomised controlled trial. *Gut* 1992;33:922-8 [1353742]

Bairati, 1992:

Bairati I, Roy L, Meyer F Double-blind, randomized, controlled trial of fish oil supplements in prevention of recurrence of stenosis after coronary angioplasty. *Circulation* 1992 Mar;85:950-6 [1537131]

Greenfield, 1993:

Greenfield SM, Green AT, Teare JP, Jenkins AP, Punchard NA, Ainley CC, Thompson RP A randomized controlled study of evening primrose oil and fish oil in ulcerative colitis. *Aliment Pharmacol Ther* 1993 Apr;7:159-66 [8485269]

Lau, 1993:

Lau CS, Morley KD, Belch JJ Effects of fish oil supplementation on non-steroidal anti-inflammatory drug requirement in patients with mild rheumatoid arthritis—a double-blind placebo controlled study. *Br J Rheumatol* 1993 Nov;32:982-9 [8220938]

Lau, 1995:

Lau CS, McLaren M, Belch JJ Effects of fish oil on plasma fibrinolysis in patients with mild rheumatoid arthritis. Clin Exp Rheumatol 1995 Jan-Feb;13:87-90 [7774110]

Nye, 1990:

Nye ER, Ablett MB, Robertson MC, Ilsley CD, Sutherland WH Effect of eicosapentaenoic acid on restenosis rate, clinical course and blood lipids in patients after percutaneous transluminal coronary angioplasty. Aust N Z J Med 1990 Aug;20:549-52 [2222347]

Singh, 1997:

Singh RB, Niaz MA, Sharma JP, Kumar R, Rastogi V, Moshiri M Randomized, double-blind, placebo-controlled trial of fish oil and mustard oil in patients with suspected acute myocardial infarction: the Indian experiment of infarct survival-4. Cardiovasc Drugs Ther 1997;11:485-91 [9310278]

Skoldstam, 1992:

Skoldstam L, Brjesson O, Kjllman A, Seiving B, Akesson B Effect of six months of fish oil supplementation in stable rheumatoid arthritis. A double-blind, controlled study. Scand J Rheumatol 1992;21:178-85 [1529284]

Thien, 1993:

Thien FC, Mencia-Huerta JM, Lee TH Dietary fish oil effects on seasonal hay fever and asthma in pollen-sensitive subjects. Am Rev Respir Dis 1993;147:1138-43 [8484622]

Johansen, 1999:

Johansen O, Brekke M, Seljeflot I, Abdelnoor M, Arnesen H N-3 fatty acids do not prevent restenosis after coronary angioplasty: results from the CART study. Coronary Angioplasty Restenosis Trial. J Am Coll Cardiol 1999;33:1619-26 [10334433]

Nilsen, 2001:

Nilsen DW, Albrektsen G, Landmark K, Moen S, Aarsland T, Woie L Effects of a high-dose concentrate of n-3 fatty acids or corn oil introduced early after an acute myocardial infarction on serum triacylglycerol and HDL cholesterol. Am J Clin Nutr 2001 Jul;74:50-6 [11451717]

ALPHA OMEGA (EPA DHA), 2010:

Kromhout D, Giltay EJ, Geleijnse JM n-3 Fatty Acids and Cardiovascular Events after Myocardial Infarction. N Engl J Med 2010 Nov 18;363:2015-2026 [20929341] 10.1056/NEJMoa1003603

Risk and Prevention Study, 2013:

Roncagliani MC, Tombesi M, Avanzini F, Barlera S, Caimi V, Longoni P, Marzona I, Milani V, Silletta MG, Tognoni G, Marchioli R n-3 fatty acids in patients with multiple cardiovascular risk factors. N Engl J Med 2013 May 9;368:1800-8 [23656645] 10.1056/NEJMoa1205409

Efficacy of n-3 polyunsaturated fatty acids and feasibility of optimizing preventive strategies in patients at high cardiovascular risk: rationale, design and baseline characteristics of the Rischio and Prevenzione study, a large randomised trial in general practice. Trials 2010;11:68 [20509875]

GISSI HF fatty acid, 2008:**n3-PUFA-HF, :****Bonnema, 1995:**

Bonnema SJ, Jespersen LT, Marving J, Gregersen G. Supplementation with olive oil rather than fish oil increases small arterial compliance in diabetic patients. Diabetes, Nutrition and Metabolism Clinical and Experimental 1995;8:81-87

Connor, 1993:

Connor WE, Prince MJ, Ullmann D, Riddle M, Hatcher L, Smith FE, Wilson D The hypotriglyceridemic effect of fish oil in adult-onset diabetes without adverse glucose control. Ann N Y Acad Sci 1993 Jun 14;683:337-40 [8352456]

Sacks (HARP), 1995:

Sacks FM, Stone PH, Gibson CM, Silverman DI, Rosner B, Pasternak RC Controlled trial of fish oil for regression of human coronary atherosclerosis. HARP Research Group. J Am Coll Cardiol 1995 Jun;25:1492-8 [7759696]

Belluzzi, 1996:

Belluzzi A, Brignola C, Campieri M, Pera A, Boschi S, Miglioli M Effect of an enteric-coated fish-oil preparation on relapses in Crohn's disease. N Engl J Med 1996 Jun 13;334:1557-60 [8628335]

Belluzzi A, Brignola C, Campieri M, Pera A, Boschi S, Miglioli M Effect of an enteric-coated fish-oil preparation on relapses in Crohn's disease. N Engl J Med 1996 Jun 13;334:1557-60 [8628335]

Reis, 1991:

Reis GJ, Boucher TM, Sipperly ME, Silverman DI, McCabe CH, Baim DS, Sacks FM, Grossman W, Pasternak RC Randomised trial of fish oil for prevention of restenosis after coronary angioplasty. Lancet 1989 Jul 22;2:177-81 [2568519]

2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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