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

TrialResults-center www.trialresultscenter.org

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 angina7ieq	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-insulindependant 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 infarctionage/p	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 + DHAdaily), 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 colitismag	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 arthritisp	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 agoe/pj	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 cholesterollowering 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
Pikasol vs placebo			
Bonnema , 1995 n=14/14 follow-up: 24 months	Pikasol 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

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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.

TrialResults-center is non-profit and self-funded.