

Clinical trials of omega-3 fatty acids for cardiovascular prevention in patients at low risk

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1 omega-3 Fatty acids

Trial	Treatments	Patients	Trials design and methods
diet vs control			
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			
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)	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
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
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
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
Dry , 1991 n=6/6 follow-up: 12 months	Liparmony (1g/d EPA + DHA) versus placebo	people with asthma	Parallel groups double blind France

continued...

Trial	Treatments	Patients	Trials design and methods
Geusens , 1994 n=60/30 follow-up: 12 months	high and low 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
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
MaxEPA vs placebo			
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
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
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

References

Mate-Jimenez, 1991:

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](#)]

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](#)]

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](#)]

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](#)]

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](#)]

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](#)]

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](#)]

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](#)]

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](#)]

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