Clinical trials of fish oil

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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

More details and results :

- omega-3 fatty acids for cardiovascular prevention in all type of patients at http://www.trialresultscenter.org/go-Q121
- omega-3 fatty acids for cardiovascular prevention in patients at high risk at http://www.trialresultscenter.org/go-Q123
- omega-3 fatty acids for cardiovascular prevention in pateints at low risk at http://www.trialresultscenter.org/go-Q124

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2 cardiac arrest

Trial	Treatments	Patients	Trials design and methods
fish oil vs placebo			
Raitt , 2006 [NCT00004558] n=100/100 follow-up:	Fish oil 1.3g versus placebo (olive oil)	-	parallel group double blind
SOFA , 2006 [NCT00110838] n=273/273 follow-up: 356 days (14-379)	Fish oil 0.9g versus placebo (High-oleic sunflower oil)	-	Parallel groups double blind Europe
Leaf , 2005 n=200/202	Fish oil 2.6g versus placebo (olive oil)	-	

More details and results :

- omega-3 fatty acids for cardiac arrest in patients with an implantable cardioverter defibrillator at http://www.trialresultscenter.org/go-Q306

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3 patients with implantable cardioverter defibrillators

Trial	Treatments	Patients	Trials design and methods
fish oil vs placebo			
Raitt , 2006 [NCT00004558] n=100/100 follow-up:	Fish oil 1.3g versus placebo (olive oil)	-	parallel group double blind
SOFA , 2006 [NCT00110838] n=273/273 follow-up: 356 days (14-379)	Fish oil 0.9g versus placebo (High-oleic sunflower oil)	-	Parallel groups double blind Europe
Leaf , 2005 n=200/202	Fish oil 2.6g versus placebo (olive oil)	-	

More details and results :

- omega-3 fatty acids for patients with implantable cardioverter defibrillators in all type of patients at http://www.trialresultscenter.org/go-Q383

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