SU.FOL.OM3 - SU.FOL.OM3 Trial: B-vitamins and N-3 polyunsaturated fatty acids supplementation and risk of recurrence of cardiovascular events

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General

Identification

Detailed name	SU.FOL.OM3 Trial: B-vitamins and N-3 polyunsaturated fatty acids supplementation and risk of recurrence of cardiovascular events
Sign or acronym	SU.FOL.OM3
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCPPRB No 1933 -CNIL No 901230

General Aspects

Medical area	Cardiology
Health determinants	Nutrition Social and psychosocial factors
Keywords	cardiovascular diseases, cerebrovascular accident (CVA), randomized trial, secondary prevention

Scientific investigator(s) (Contact)

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Organization	Inserm, INRA, CNAM

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Mixed
Details	Inserm, Ministère de la Recherche, fondation coeurs et artères, Pierre Fabre, Danone, Candia, Eprova

Governance of the database

Sponsor(s) or organisation(s) responsible	Inserm
Organisation status	Public
Sponsor(s) or organisation(s) responsible	INRA
Organisation status	Public
Sponsor(s) or organisation(s) responsible	CNAM
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Université Paris XIII

Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	Yes
Details	Performed at group level (clusters)
Additional information regarding sample selection.	Subject inclusion procedure: subjects are recruited through a national network of over 686 clinicians working in hospitals, privately or in cardiovascular rehabilitation centers; these cardiologists, neurologists or internists report to national SU.FOL.OM 3 coordinators all patients who meet the inclusion and exclusion criteria. Then, the patients are contacted by the SU.FOL.OM 3 trial physicians, who shall invite them for an appointment for their definitive inclusion in one of the 166 SU.FOL.OM 3 local centers. During this appointment, the subjects benefit from a blood test so as to determine different biological parameters and take anthropometric measurements; they shall also fill in a dietary questionnaire and receive B vitamins and/or omega 3 supplements in the form of soft capsules made specifically for the trial.Double blind randomized trial: the subjects included are randomly split into four groups, receiving either a combination of B vitamins: folates (in the form of 5-methyl-tetra-hydro-folates) (560 µg/day), vitamin B6 (3 mg/day) and vitamin B12 (20 µg/day) and an "omega 3" placebo, or omega 3 polyunsaturated fatty acids (600 mg/day, in the form of E.P.A./D.H.A. 2 :1) and a "B vitamins" placebo, or the combination of group B vitamins and omega 3 polyunsaturated fatty acids, or an "omega 3" placebo and "B vitamins" placebo.

Database objective

Main objective	Primary objectives: check the impact of folate (and

	vitamin B6 or B12) and/or omega 3 supplements in preventing the recurrence of ischemic disorders in patients with a background of ischemic cardio or cerebrovascular history. Secondary objective: assess the role of certain genetic mutations in the ability of supplements to reduce the risk of cardiovascular diseases.
Inclusion criteria	Subjects aged between 45 and 80, having presented a myocardial infarction, unstable angina or stroke in the period preceding their inclusion (event occurred at least one month and at the most one year prior to inclusion). Exclusion criterion: subjects that have to take B12, folic acid or B6 supplements, subjects under methotrexate treatment, subjects suffering from a life-threatening non-cardiovascular disease over the 5 years of the study, severe chronic kidney disease sufferers.
Population type	
Age	Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	09/2003
Date of last collection (YYYY or MM/YYYY)	01/2010
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2501

Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Clinical examination upon inclusion and during follow-up (yearly)Information gathered during the clinical examination: blood pressure, clinical examination focused on the disease, anthropometry
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Clinical examination upon inclusion and during follow-up (yearly)Information gathered during the clinical examination: blood pressure, clinical examination focused on the disease, anthropometry
Biological data (detail)	Blood: plasma homocysteine levels, plasma vitamin B12 levels, plasma pyridoxal phosphate levels, plasma and erythrocyte folate levels, genetic polymorphism of the gene coding for MTHFR, lipid count and blood glucose levels.
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Blood cells isolated DNA Others
Details of biobank content	serum bank, plasma bank, DNA bank, Buffy coat
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	The subjects benefit from annual clinico-biological follow-up from the technicians and physicians in the SU.FOL.OM 3 team. All events concerning the health of the subjects (changes in treatment, hospitalization, surgery, recurrences, death, etc.) are gathered at annual appointments in the SU.FOL.OM 3 local centers or through bi-annual

	questionnaires; additional information is also obtained through bi-annual questionnaires; and from GPs or consultants who care for the patients.Data collected by:- self-questionnaire: (1) health events, progression in certain risk factors and lifestyle habits, (2) dietary questionnaire.- clinical examination: blood pressure, clinical examination focused on the disease, anthropometry- information provided by a third party on cardiovascular or neurovascular health events occurring
Quality procedure(s) used	Coherency query during and after entry of computer data.Management of missing data by return to source file or return to patient.Reminders sent out to physicians for follow-up appointments.Reminders sent out to subjects for follow-up appointments.Internal quality audit performedThe patients are informed of what use will be made of their data.
Participant monitoring	Yes
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/SUFOLOM3
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=SU.FOL.OM3+OR+SU-FOL-OM3+OR+SUFOLOM3+OR+23352552[uid]+OR+24965307[uid]
Description	List of publications in Pubmed
Link to the document	http://www.hal.inserm.fr/SUFOLOM3
Link to the document	http://www.ncbi.nlm.nih.gov/entrez/eutils/erss.cgi?rss_guid

Access

Terms of data access (charter for data provision, format of data, availability delay)	Possible use of data by academic teams (contractual conditions) Data cannot be used by manufacturers Involvement in a cohort network: network of trials on intervention by folates (55 000 SJ au TAL)

Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only