

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

Head :Hercberg Serge, Unité de Recherche en Epidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Galan Pilar, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

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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)

Name of the director Hercberg

Surname Serge

Address UFR SMBH, 74 rue Marcel Cachin, 93017 Bobigny

Phone + 33 (0)1 48 38 89 32

Email s.hercberg@uren.smbh.univ-paris13.fr

Unit Unité de Recherche en Epidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam /

Université Paris 13 (Sorbonne Paris-Cité)

Organization Inserm, INRA, CNAM

Name of the director Galan

Surname Pilar

Address UFR SMBH, 74 rue Marcel Cachin, 93017 Bobigny

Phone + 33 (0)1 48 38 89 32

Email p.galan@uren.smbh.univ-paris13.fr

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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.	<p>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.</p>
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 performed. The 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\[uid\]](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

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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