

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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Date de modification : 01/01/2020 | Version : 3 | ID : 3319

Général

Identification

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

Sigle ou acronyme SU.FOL.OM3

Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) CCPPRB No 1933 -CNIL No 901230

Thématiques générales

Domaine médical Cardiology

Déterminants de santé Nutrition
Social and psychosocial factors

Mots-clés cardiovascular diseases, cerebrovascular accident (CVA), randomized trial, secondary prevention

Responsable(s) scientifique(s)

Nom du responsable Hercberg

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Organisme	Inserm, INRA, CNAM

Collaborations

Participation à des projets, des réseaux, des consortiums Yes

Financements

Financements Mixed

Précisions Inserm, Ministère de la Recherche, fondation coeurs et artères, Pierre Fabre, Danone, Candia, Eprova

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur Inserm

Statut de l'organisation Secteur Public

Organisation(s) responsable(s) ou promoteur INRA

Statut de l'organisation Secteur Public

Organisation(s) responsable(s) ou promoteur CNAM

Statut de l'organisation Secteur Public

Organisation(s) responsable(s) ou promoteur Université Paris XIII

Statut de l'organisation Secteur Public

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données Study databases

Base de données issues d'enquêtes, précisions Cohort study

Origine du recrutement des participants A selection of health care professionals
A selection of health institutions and services

Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle Yes

Précisions Performed at group level (clusters)

Informations complémentaires concernant la constitution de l'échantillon

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.

Objectif de la base de données

Objectif principal 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.

Critères d'inclusion

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.

Type de population

Age Adulthood (45 to 64 years)
Elderly (65 to 79 years)

Population concernée Sick population

Sexe Male
Woman

Champ géographique National

Détail du champ géographique France

Collecte

Dates

Année du premier recueil 09/2003

Année du dernier recueil 01/2010

Taille de la base de données

Taille de la base de données (en nombre d'individus) [1000-10 000[individuals

Détail du nombre d'individus 2501

Données

Activité de la base Data collection completed

Type de données recueillies	Clinical data Declarative data Biological data
Données cliniques, précisions	Medical registration
Détail des données cliniques recueillies	Clinical examination upon inclusion and during follow-up (yearly)Information gathered during the clinical examination: blood pressure, clinical examination focused on the disease, anthropometry
Données déclaratives, précisions	Paper self-questionnaire
Détail des données déclaratives recueillies	Clinical examination upon inclusion and during follow-up (yearly)Information gathered during the clinical examination: blood pressure, clinical examination focused on the disease, anthropometry
Données biologiques, précisions	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.
Existence d'une bibliothèque	Yes
Contenu de la bibliothèque	Serum Plasma Blood cells isolated DNA Others
Détail des éléments conservés	serum bank, plasma bank, DNA bank, Buffy coat
Paramètres de santé étudiés	Health event/morbidity Health event/mortality

Modalités

Mode de recueil des données	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
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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

Procédures qualité utilisées

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.

Suivi des participants

Yes

Appariement avec des sources administratives

No

Valorisation et accès

Valorisation et accès

Lien vers le document

<http://www.hal.inserm.fr/SUFOLOM3>

Description

List of publications in HAL

Lien vers le 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

Lien vers le document

<http://www.hal.inserm.fr/SUFOLOM3>

Lien vers le document

http://www.ncbi.nlm.nih.gov/entrez/eutils/erss.cgi?rss_guid

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)

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)

Accès aux données agrégées

Access on specific project only

