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

Responsable(s) :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 Nutritionnele (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

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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
Prénom	Serge
Adresse	UFR SMBH, 74 rue Marcel Cachin, 93017 Bobigny
Téléphone	+ 33 (0)1 48 38 89 32
Email	s.hercberg@uren.smbh.univ-paris13.fr
Laboratoire	Unité de Recherche en Epidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)
Organisme	Inserm, INRA, CNAM

Nom du responsable	Galan
Prénom	Pilar
Adresse	UFR SMBH, 74 rue Marcel Cachin, 93017 Bobigny
Téléphone	+ 33 (0)1 48 38 89 32
Email	p.galan@uren.smbh.univ-paris13.fr
Laboratoire	Unité de Recherche en EPidémiologie Nutritionnele (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)
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 biothèque	Yes
Contenu de la biothèque	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

	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 performedThe 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]
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

Accès aux données individuelles	Access on specific project only