# 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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## Général

### Identification

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| 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

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| Domaine médical | Cardiology |
| Etude en lien avec la Covid-19 | No |
| Déterminants de santé | Medicine<br>Nutrition<br>Social and psychosocial factors |
| Mots-clés | cardiovascular diseases, cerebrovascular accident (CVA), randomized trial, secondary prevention |

### Responsable(s) scientifique(s)

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|---|---|
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| Organisme | Inserm, INRA, CNAM, université Paris 13 |
| **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 |

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| 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<br>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** | |

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| 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.<br><br>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).<br><br>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)<br>Elderly (65 to 79 years) |
| Population concernée | Sick population |
| Pathologie | I20-I25 - Ischaemic heart diseases |
| | IX - Diseases of the circulatory system |
| Sexe | Male<br>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 | [1000-10 000[ individuals |

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| nombre d'individus) | |
| Détail du nombre d'individus | 2501 |
| **Données** | |
| Activité de la base | Data collection completed |
| Type de données recueillies | Clinical data<br>Declarative data<br>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<br>Plasma<br>Blood cells isolated<br>DNA<br>Others |
| Détail des éléments conservés | serum bank, plasma bank, DNA bank, Buffy coat |
| Paramètres de santé étudiés | Health event/morbidity<br>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 |

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| | 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

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| 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

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| Charte d'accès aux données | Possible use of data by academic teams |

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| (convention de mise à disposition, format de données et délais de mise à disposition) | (contractual conditions)<br>Data cannot be used by manufacturers<br>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 |