An open label extension study to evaluate long term use of a Food for Special Medical Purposes (FSMP) in patients with mild Alzheimer*s disease who completed the Souvenir II study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36704

Source
ToetsingOnline

Brief title
Souvenir II Open Label Extension Study

Condition

- Neurological disorders NEC

Synonym
Alzheimer, Alzheimers Disease

Research involving
Human

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research

Intervention

Keyword: Alzheimer's Disease, Long term use, Medical food, Neurology

Outcome measures

Primary outcome

Compliance

Safety

Secondary outcome

Exploratory parameters include:

-Cognition

-Global function

Study description

Background summary

The protocol describes an open label extension study for those subjects completing the randomised controlled double-blind Souvenir II study or Souvenir II MEG sub-study.

The Souvenir II study was developed to confirm and extend the results of the 12-week double-blind controlled Souvenir study with a similarly designed 12-week extension period. The Souvenir study demonstrated that the multi-nutrient study product *Souvenaid®* improved 12-week memory performance both in the overall ITT (baseline MMSE 20-26, n=225) population and in the prespecified subgroup analysis of patients with very mild Alzheimer*s Disesase (AD). Furthermore, the Souvenir study showed that Souvenaid has a good safety profile and was well tolerated throughout 24 weeks of supplementation [1]. In the currently running Souvenir II study and Souvenir II MEG sub-study, a similar study population of mild to very mild AD patients (MMSE >= 20) with no current use of AD medication is included, and memory performance is again the

primary outcome.

Study objective

The purpose of this open label extension study is to gather further compliance and safety information on the longer-term (up to approximately 48 weeks) use of the study product. This will provide valuable information in addition to the findings of the so far conducted [1] and running studies (Souvenir II; NTR1975, and the S-Connect study; NTR1683) with Souvenaid which have a maximum intervention duration of approximately 24 weeks. Furthermore, the intention of the 24-week open label extension study is to provide ongoing medical nutrition therapy for subjects who completed the Souvenir II study.

Study design

A 24-week multicentre multi-country open label extension study.

Intervention

The study product is a 125ml (125kcal) once-a-day drink to be taken with breakfast. There is a choice of two flavours: vanilla and strawberry.

Study burden and risks

From a proof of concept study in 225 AD subjects with the same study product, it has been concluded that the study product has a good safety profile and is well tolerated throughout 24 weeks of supplementation. Of the procedures, venepuncture for collecting blood samples might cause bruising.
Three study visits are scheduled, the first of which is combined with the week 24 visit of the Souvenir II study or the Souvenir II MEG sub-study. For this first visit the data of the Souvenir II study or Souvenir II MEG sub-study week 24 visit is used for baseline data. For the Open Label Extension study the mental state is noted using the MMSE. During the second (week 12) study visit cognition is assessed through the memory domain z-score of the Neuropsychological Test Battery (NTB)). This is done again during the third and final visit. Furthermore a product evaluation questionnaire is completed, vital signs and weight are measured, and a blood sample is taken. During all visits, and during the telephone contacts at week 6, 18, and 2 week follow up, the overall health, occurrence of (S)AEs and changes in concomitant medication are required after and noted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Completion of 24 week study visit Souvenir II study or the Souvenir II MEG sub-study
Availability of responsible caregiver
Written informed consent of subject and caregiver

Exclusion criteria

Use of other investigational products
Alcohol or drug abuse in opinion of the investigator
Uncertainty about willingness, ability, or medical status of subject to comply with protocol requirements

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2010
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	17-09-2010
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	21-10-2010
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	07-02-2011

Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	13-05-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	19-08-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32008.072.10