Souvenir II Open Label Extension study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26602

Source
Nationaal Trial Register

Brief title
Souvenir II OLE

Health condition

Alzheimer’s Disease

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Compliance and safety:

1. Compliance as measured by the daily study product intake and product evaluation on taste and convenience;

2. Safety as measured by the number of (Serious) Adverse Events.

Secondary outcome

N/A

Study description

Background summary

In this trial the compliance and safety with a Medical Food will be monitored in Alzheimer's Disease. The study is performed in 31 centers in the Netherlands, Belgium, Germany, Spain, Italy and France.

Study objective

Collect long term data on compliance and safety of the study product in patients with mild Alzheimer's disease who completed the Souvenir II study.

Study design

V0 (screening & baseline);

V1 (week 12);

V3 (week 24).

Intervention

Duration of intervention: 24 weeks.

Intervention: All participants will receive daily 125 ml of Souvenaid®. Souvenaid® is a 125ml (125kcal) once-a-day milk based drink. Souvenaid® contains FortasynTM Connect [a specific combination of nutrients].

Contacts

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Eligibility criteria

Inclusion criteria

1. Completion of 24 week study visit Souvenir II study;

2. Availability of responsible caregiver;

3. Written informed consent of subject and caregiver.

Exclusion criteria

1. Use of other investigational products;

2. Alcohol or drug abuse in opinion of the investigator;

3. Investigator’s uncertainty about willingness, ability, or medical status of subject to comply with protocol requirements.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2010
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	15-10-2010
Application type:	First submission

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
NTR-new	NL2456
NTR-old	NTR2571
Other	Danone Research - Centre for Specialised Nutrition : Alz.1.C/F
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Scheltens et al., 2010.
Olde Rikkert et al. J of Alzheimers Dis. 2015 44: 471–480.