An observational study to evaluate the use of Souvenaid in real world daily clinical practice in patients with early Alzheimer’s Disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26650

Source
Nationaal Trial Register

Brief title
AWARE

Health condition

early Alzheimer's Disease
Souvenaid
daily clinical practice
IADL

Sponsors and support

Primary sponsor: Nutricia Advanced Medical Nutrition
Zoetermeer, The Netherlands
Source(s) of monetary or material Support: Nutricia Advanced Medical Nutrition
Zoetermeer, The Netherlands

Intervention

Outcome measures

Primary outcome

IADL (Amsterdam IADL Questionnaire).

Secondary outcome

Compliance.

Study description

Background summary

Currently recorded and published data regarding the use of Souvenaid result from controlled clinical trials in controlled patient populations. This observational study AWARE is developed to evaluate the use of Souvenaid in real world daily clinical practice in patients with early Alzheimer’s Disease. The AWARE study is an open-label observational multi-centre study in real world daily clinical practice in The Netherlands.

Study objective

The primary endpoint is to evaluate the use of Souvenaid in patients with early AD in real world clinical practice by assessing the effect of Souvenaid on patients’ functioning on instrumental activities of daily living (IADL) as perceived by the caregiver.

Study design

1. Baseline;

2. 6 months;

3. 12 months.

Intervention

1 Souvenaid per day.

Contacts

Public

Nutricia Advanced Medical Nutrition
Postbus 445
Karina Roozen
Zoetermeer 2700 AK
The Netherlands
+31 (0)6 55860755
Scientific
Nutricia Advanced Medical Nutrition
Postbus 445
Karina Roozen
Zoetermeer 2700 AK
The Netherlands
+31 (0)6 55860755

Eligibility criteria

Inclusion criteria

1. The patient is diagnosed with early AD as judged by the HCP (based on criteria used in the memory clinic);

2. The patient has a MMSE score of >20;

3. The HCP has decided to prescribe Souvenaid (up to 1 month ago);

4. A responsible caregiver of the patient is available;

5. The patient and caregiver are willing to give written approval of collecting anonymous data.

Exclusion criteria

1. The patient participates in any other study involving investigational or marketed products concomitantly or has participated in such a study within two weeks prior to entry into the study;

2. HCP’s uncertainty about medical status, willingness or ability of the patient to comply with protocol requirements.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2013
Enrollment:	315
Type:	Actual

Ethics review

Positive opinion

Date:	13-02-2013
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	NL3685
NTR-old	NTR3855
Other	METC IRBN te Nijmegen : IRBN2012014 HdJ 1
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A