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

Gepubliceerd: 13-02-2013 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26650

Bron
NTR

Verkorte titel
AWARE

Aandoening

early Alzheimer's Disease
Souvenaid
daily clinical practice
IADL

Ondersteuning

Primaire sponsor: Nutricia Advanced Medical Nutrition
Zoetermeer, The Netherlands
Overige ondersteuning: Nutricia Advanced Medical Nutrition
Zoetermeer, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

IADL (Amsterdam IADL Questionnaire).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline;

2. 6 months;

3. 12 months.

Onderzoeksproduct en/of interventie

1 Souvenaid per day.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-02-2013
Aantal proefpersonen:	315
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3685
NTR-old	NTR3855
Ander register	METC IRBN te Nijmegen : IRBN2012014 HdJ 1
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A