Rivastigmine as a treatment in delirium; a pilot study

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Given the presumed cholinergic deficiency the cholinergic drug rivastigmine might be a suitable drug for treatment of delirium

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28018

Bron
NTR

Verkorte titel
N/A

Aandoening

delirium stroke (dutch; delier beroerte)

Ondersteuning

Primaire sponsor: Novartis
Overige ondersteuning: Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Presence of delirium measured with confusion assessment method and delirium rating scal

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Delirium is a common disorder in the early phase of stroke. Given the presumed cholinergic deficiency in delirium, we tested treatment with the acetylcholinesterase inhibitor rivastigmine.

Methods:

This pilot study was performed within an epidemiological study. In 527 consecutive stroke patients presence of delirium was assessed during the first week with the confusion assessment method. Severity was scored with the delirium rating scale (DRS). Sixty-two patients developed a delirium in the acute phase of stroke. Only patients with a severe and persistent delirium were enrolled in the present study. In total 26 fulfilled these criteria of whom 17 were treated with orally administered rivastigmine. Eight patients could not be treated because of dysphagia and one because of early discharge.

Results:
No major side effects were recorded. In 16 patients there was a considerable decrease in severity of delirium. The mean duration of delirium was 6.7 days (range; 2-17).

Conclusions:

Rivastigmine is safe in stroke patients with delirium even after rapid titration. In the majority of patients the delirium improved after treatment. A randomized controlled trial is needed to establish the usefulness of rivastigmine in delirium after stroke.

Doel van het onderzoek

Given the presumed cholinergic deficiency the cholinergic drug rivastigmine might be a suitable drug for treatment of delirium

Onderzoeksopzet

- Each treated patient was followed untill the delirium was gone

Onderzoeksproduct en/of interventie

Rivastigmine 1.5 b.i.d, with an increase every other day with 3 mg to a maximum of 6 mg

b.i.d

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Recent stroke

2. Persistent delirium

3. Severe delirium

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior adverse effects of rivastigmine

2. Severe renal failure

3. Age < 18 years

4. Women of child bearing potential

5. Use of any other investigational agent in the last 30 days

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2004
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-08-2008
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	NL1337
NTR-old	NTR1395
Ander register	Medical ethical commitee Tilburg the Netherlands : 0307
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A