

# Rivastigmine as a treatment in delirium; a pilot study

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28018

### Source

NTR

### Brief title

N/A

### Health condition

delirium stroke (dutch; delier beroerte)

## Sponsors and support

**Primary sponsor:** Novartis

**Source(s) of monetary or material Support:** Novartis

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

- Duration of delirium

- Other medication needed

## Study description

### Background summary

#### 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.

### Study objective

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

### Study design

- Each treated patient was followed until the delirium was gone

## Intervention

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

## Contacts

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1. Recent stroke
2. Persistent delirium
3. Severe delirium

### Exclusion criteria

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

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2004
Enrollment:	20
Type:	Actual

## Ethics review

Positive opinion	
Date:	05-08-2008
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	NL1337
NTR-old	NTR1395
Other	Medical ethical committee Tilburg the Netherlands : 0307
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A