

Driving ability after neurological diseases: driving behavior and therapy

Submission date 27/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/05/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/12/2006	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.refonet.de/projekte/laufendeprojekte_5010.php

Contact information

Type(s)

Scientific

Contact name

Prof Dr. Hans Karbe

Contact details

Neurological Rehabilitation Center Godeshoehe e.V.

Section Neuropsychology

Waldstr. 2-10

Bonn

Germany

53177

+49 (0)228 381207

h.karbe@godeshoehe.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

05010

Study information

Scientific Title

Study objectives

Driving ability, measured by a test of driving behavior after the intervention, improves more after a neuropsychological training with additional individual driving training than after a neuropsychological training with placebo intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Bonn, Medical Faculty (under review as of 02/05/2006)

Study design

Randomised clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Stroke, brain injury

Interventions

Group A: Individual driving training and neuropsychological training

Group B: Neuropsychological training and placebo intervention (computer education)

Pre/post: test of driving behavior and neuropsychological assessment.

Additional post: interview with patient about compensational strategies and interview with driving instructor concerning patients performance during driving lessons.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2006

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Neurological, annuity assured patients (phase d, Barthel-Index >80) with stroke or brain injury and written informed consent.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60 participants (30 group A, 30 group B)

Key exclusion criteria

1. Hemiparesis
2. Seizure disorder
3. Visual field failures in terms of driving licence ordinance (FeV appendix 6)
4. Psychiatric history and important cognitive impairment as orientation disorder and a lack of understanding of instructions
5. Patients with extreme abnormal driving experience (no car driving in the last year or more than 70,000 km per year)

Date of first enrolment

01/04/2006

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Germany

Study participating centre
Neurological Rehabilitation Center Godeshoehe e.V.
Bonn
Germany
53177

Sponsor information

Organisation
Refonet (Germany)

Sponsor details
c/o Dr. Hartmut Pollmann
Postfach 10 07 63
Bad Neuenahr-Ahrweiler
Germany
53445
+49 (0)264 1906212
service@refonet.de

Sponsor type
Research organisation

Website
<http://www.refonet.de/>

ROR
<https://ror.org/04yeh2x21>

Funder(s)

Funder type
Research organisation

Funder Name
Rehabilitations - Research Network of the German Pension Insurance Fund Rhineland - Refonet
Germany (Forschungsnetzwerk der Deutschen Rentenversicherung Rheinland - Refonet) Project
number: 05010

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration