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Evaluation of Dutch Integrated Stroke Service Experiments

Submission date	Recruitment status	[_] Prospectively registered
26/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/08/2011	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.zonmw.nl

Contact information

Type(s)
Scientific

Contact name
Prof Robbert Huijsman

Contact details
Inst Health Policy & Managment
Erasmus Unversity Rotterdam
Burgemeester Oudlaan 50
Rotterdam
Netherlands
3000DR
+31 10 4088555
r.huijsman@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
EDISSE

Study objectives
Stroke services lead to better and more effective, efficient and patient-directed care for stroke patients compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approvals received from Local Medical Ethics Committees for all six regional services at all hospitals involved between May and September 1999.

Case regions:
1. Heemstede, Spaarne Hospital: Medical Ethics Committee of Spaarne Hospital
2. Delft, Hospital Reinier de Graaf Groep: Medical Ethics Committee for South West Holland
3. Nijmegen, Canisius Wilhelmina Hospital: Ethics Committee of Canisius

Control regions:
1. Amsterdam, Saint Lucas Andreas Hospital: Medical Ethics Committee of Saint Lucas Andreas Hospital
2. Hilversum, Hilversum Hospital: Medical Ethics Committee of Hilversum Hospital
3. Leiderdorp, Rijnland Hospital: Medical Ethics Committee of Rijnland Hospital

Central registration:
1. Central Committee for Patient-Related Research: annual reports and overviews of decisions by local MECs
2. The Central Committee on Research Involving Human Subjects (CCMO)

Study design
Prospective, non-randomized controlled trial.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ischemic stroke

Interventions
The experimental stroke service settings were those that provided Integrated Stroke unit and Stroke services care as defined by an expert consensus committee. Methodologically, the assessment of integrated stroke services is the evaluation of a complex mixture of interventions at the organizational, professional and patient levels. It needs careful definition, or at least a full description to allow for a transparent (cost-) effectiveness analysis. Formally, Dutch stroke services are defined as a network of service providers working together in an organized way to proved adequate services in all stages of the follow-up of stroke patients. It includes a hospital stroke unit. An expert group made this broad definition more explicit, defining a core set and an optimal set of criteria. It emphasizes a setting integrating all relevant institutions: hospitals, nursing homes, rehabilitation centers, general practitioners and home care providers working together to provide multidisciplinary, coordinated care through organized patient transfers and protocols. This definition is in accordance with international views.

We compared all consecutively hospitalized stroke patients in three experimental stroke service settings (Delft, Haarlem and Nijmegen, 411 patients in total) with concurrent patients receiving conventional stroke care (187 patients) over 6 months follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Health-related quality-of-life (QALIES) at two and six months
2. Cumulative total societal costs at three months (direct and indirect costs)
3. "Length-of-stay" as the most important cost driver

Secondary outcome measures
1. Other neurological health outcomes (Glasgow Coma Scale, 30 item version of the Sickness Impact Profile [SA-SIP30], Cambridge Cognitive Examination, modified Rankin Scale [mRS], The Barthel Index [BI])
2. Care satisfaction
3. Indirect medical costs
4. Residence
5. Quality of care

A qualitative study also observed the characteristics of the regional services.

Overall study start date
01/09/1999

Completion date
31/05/2000

Eligibility

Key inclusion criteria
All patients in these experimental settings were compared to similar concurrent patients from general hospitals in three other Dutch regions. The latter were selected from a group of 23 hospitals participating in a previous national study. Based on the data collected in this already completed study, three hospitals were selected as representing the average Dutch patient, receiving the average current level of Dutch stroke care. The criteria for this selection were:
1. The average age of patients
2. Duration of hospital stay
3. Case-fatality
4. Barthel Index at discharge
5. Destination after discharge

All consecutive hospital patients admitted in a region with an acute first or recurrent ischemic stroke or Transient Ischemic Attack (TIA) were included.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
A minimum of 75 and a maximum of 100 patients per cluster; 411 patients were registered.

Key exclusion criteria
Dead on arrival.

Date of first enrolment
01/09/1999

Date of final enrolment
31/05/2000

Locations

Countries of recruitment
Netherlands

Study participating centre

Inst Health Policy & Managment
Rotterdam
Netherlands
3000DR

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw)

Sponsor details
Laan van Nieuw Oost Indië 334
Postbox 93 245
The Hague
Netherlands
2509 AE

Sponsor type
Research organisation

Website
http://www.zonmw.nl/en/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	26/02/2003		Yes	No
Results article	Results:	01/03/2004		Yes	No
Results article	Results:	01/03/2004		Yes	No
Results article	Results:	01/09/2004		Yes	No
Results article	Results:	03/11/2004		Yes	No
Results article	Results:	01/06/2005		Yes	No