

Evaluation of Dutch Integrated Stroke Service Experiments

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 provide 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes