The International Stroke Trial database

Peter A.G. Sandercock[1], Maciej Niewada[2,3], Anna Członkowska[2,3], on behalf of the International Stroke Trial Collaborative Group

[1] Department of Clinical Neurosciences, University of Edinburgh, Department of Clinical Neurosciences, Western General Hospital, Edinburgh EH4 2XU, UK

[2] Department of Clinical and Experimental Pharmacology, Warsaw Medical University, Poland, Krakowskie Przedmieście 26/28, 00-927 Warsaw, Poland

[3] 2nd Department of Neurology, Institute of Psychiatry and Neurology, 9 Sobieskiego 02-957, Warsaw, Poland

Email addresses:

Peter A.G. Sandercock: Peter.Sandercock@ed.ac.uk

Maciej Niewada: maciej.niewada@wum.edu.pl

Anna Członkowska: czlonkow@ipin.edu.pl

[§]Corresponding author

Professor Peter Sandercock

Professor of Medical Neurology, Department of Clinical Neurosciences

Western General Hospital, Edinburgh, EH4 2XU, UK

Tel: +44 131 537 2928 (secretary), Fax +44 131 332 5150

Email. Peter.Sandercock@ed.ac.uk

Abstract

Background: Planning stroke clinical trials should be based on readily available robust data. The International Stroke Trial (IST) was one the biggest randomised trials in acute stroke. Methods: Available data on variables assessed at randomisation, at the early outcome point (14-days after randomisation or prior discharge) and at 6-months were extracted and made publically available. Results and Conclusions: The IST provides an excellent source of primary data easy-to-use for sample size calculations and preliminary analysis necessary for planning good quality trial.

Background

The International Stroke Trial (IST) was conducted between 1992 and 1996. It was a large, prospective, randomised controlled trial, with 100% complete baseline data and over 99% complete follow-up data. The aim of the trial was to establish whether early administration of aspirin, heparin, both or neither influenced the clinical course of acute ischaemic stroke. [1] This large, high quality data set gave opportunity to explore differences in stroke clinical course, outcome and prognostic factors. The large sample and its international (Table 1) nature gave the prospect of producing results of wide relevance.

Nineteen thousand four hundred and thirty five patients were randomised, in whom the final diagnosis was confirmed as ischaemic stroke in 17370; clinically definite stroke of unknown pathological type in 992; and haemorrhagic stroke or other diagnosis in 628 patients. The inclusion criteria were: clinical diagnosis of acute ischaemic stroke, with onset within the previous 48 hours and no clear indication for, or clear contraindication to, treatment with aspirin or subcutaneous heparin.

The data were collected, entered in a database and checked for validity at the trial coordinating centre in Edinburgh, Scotland.

Methods

We make available data on variables assessed at randomisation, at the early outcome point (14-days after randomisation or prior discharge) and at 6-months.

Results and Discussion

We extracted and make online available the following baseline data: age, gender, time from onset to randomisation, presence or absence of atrial fibrillation (AF), aspirin administration within 3 days prior to randomisation, systolic blood pressure at randomisation, level of consciousness and neurological deficit. The deficits were classified as one of the Oxfordshire Community Stroke Project (OCSP) categories: total anterior circulation syndrome (TACS), partial anterior circulation syndrome (PACS), posterior circulation syndrome (POCS) and lacunar syndrome (LACS). We extracted events within 14 days on: the occurrence of recurrent stroke, pulmonary embolism, and death (date and cause of death). At 6 months we extracted, degree of recovery, place of residence and current use of antiplatelet or anticoagulant drugs and death (date and cause of death). The cause of death was classified as: due to initial stroke, recurrent ischaemic stroke, recurrent haemorrhagic stroke, pneumonia, coronary artery disease, pulmonary embolism, other vascular cause or a nonvascular cause. Patients were assigned to one of 6 categories according to the place of residence at 6 months following stroke: own home, relatives home, residential care, nursing home, other hospital departments or unknown. All variables name and corresponding description is given in Table 2.

Anonymisation

Data set is fully anonymous in a manner that can easily be verified any user of the data set. Publication of the data set clearly and obviously presents no risk to study participants.

Conclusions

Planning stroke clinical trials should be based on readily available robust data. The IST provides an excellent source of primary data easy-to-use for sample size calculations and preliminary analysis necessary for planning good quality trial.

Competing interests

The trial was designed, conducted, analyzed, and reported independently of all sponsors. P.S., M.N., A.C. have received honoraria and travel expenses to lecture at conferences and pharmaceutical advisory meetings, but neither holds any consultancy with, or financial interest in, a pharmaceutical company, nor are they aware of any other potential conflict of interest.

Authors' contributions

P.S. was the main researcher in the IST responsible for design, conducting and presentation of the study results. M.N. and A.C. were involved in preparation of database and data dictionary for publication and help to draft the manuscript. All authors read and approved the final manuscript.

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References

1. International Stroke Trial Collaborative Group: **The International Stroke Trial a randomized trial of aspirin, subcutaneous heparin, both or neither among 19 435 patients with acute ischemic stroke.** *Lancet* 1997, **349**:1569-1581

Tables

Table 1 - Country codes used in International Stroke Trial.

Country	Code
Albania	43
Argentina	29
Australia	01
Belgium	03
Brazil	42
Bulgaria	04
Canada	05
Chile	06
Czech Republic	07
Denmark	08
Ireland	09
Finland	10
France	11
Georgia	32
Germany	12
Greece	31
Hong Kong	30
Hungary	36
India	37
Indonesia	41
Israel	13
Italy	14
Japan	38
Latvia	39
Malaysia	40
Netherlands	15

New Zeland	16
Norway	17
Poland	18
Portugal	19
Romania	33
Singapore	34
Slovak Republic	44
Slovenia	20
South Africa	21
Spain	22
Sri Lanka	23
Sweden	24
Switzerland	25
Thailand	26
Turkey	35
UK	27
USA	28

Table 2 - Variables names and comments.

See additional files section: Additional file 2 – IST_variables.pdf

Table 3. Provisional categories for non compliers.

1.	Should not have been randomised
2.	Refused treatment
3.	Initial event not a stroke
4.	Haemorrhagic stroke
5.	Non compliers
6.	Discharged after 14 days
7.	Discharged up to 14 days
8.	Died prior to receiving the study drug(s)
9.	Died after receiving the study drug(s)
10.	Recurrent stroke / pulmonary embolism
11.	Clinical decision
11a.	Suspected abnormality
11b.	Withdrawn as dying
11c.	Pre-existing condition
11d.	Stated abnormal PTT
11e.	Stated surgery
11f.	Stated atrial fibrillation
12.	Administration problem
13.	Missed out more than 3 doses
14.	Side effect
14a.	Refused Treatment
14b.	Discharged
14c.	Administration problem
14d.	Clinical decision
14e.	Recurrent stroke
14f.	Haemorrhagic stroke

Additional files

Additional file 1 – IST_data.csv

File format: csv- comma separated values

Database with information completed in IST.

Additional file 2 – IST_variables.pdf

Variables names and short description of coding.