

Trial of intensified versus standard medical therapy in elderly patients with congestive heart failure

Submission date 12/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2018	Condition category Circulatory System	<input type="checkbox"/> 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

Trial of Intensified versus standard Medical therapy in Elderly patients with Congestive Heart Failure

Acronym

TIME-CHF

Study objectives

Intensified, N-terminal B-type natriuretic peptide (NT-BNP) guided therapy is more effective than standard, symptom guided therapy in Congestive Heart Failure (CHF) patients aged greater than or equal to 75 years as compared to CHF patients aged 60 - 74 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Congestive heart failure

Interventions

Medical therapy of congestive heart failure as defined in current guidelines, either guided by symptoms only or symptoms and NT-BNP levels

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. All cause hospitalisation free survival after 18 months
2. Quality of life after 18 months

Key secondary outcome(s)

1. Primary endpoints after 12 months
2. Components of primary endpoints
3. Overall costs and use of health care resources
4. Cost-effectiveness
5. Patients' preferences regarding treatment
6. Effects of baseline characteristics on outcome
7. Prediction of tolerability and effect of medication

Completion date

31/05/2008

Eligibility

Key inclusion criteria

1. Heart failure patients aged greater than 60 years
2. New York Heart Association (NYHA) greater than or equal to II
3. CHF hospitalisation within last year
4. NT-BNP level greater than 800 pg/ml (greater than or equal to 75 years), 400 pg/ml (60 - 74 years)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Serum creatinine greater than 220 µmol/l
2. Valve disease needing surgery
3. Disease other than cardiovascular limiting life-expectancy less than 3 years
4. No informed consent

Date of first enrolment

01/12/2002

Date of final enrolment

31/05/2008

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Charity

Funder Name

Horten Foundation (Switzerland)

Funder Name

Unrestricted grants from different pharmaceutical companies:

Funder Name

AstraZeneca Schweiz

Alternative Name(s)

AstraZeneca Suisse, AstraZeneca Svizzera, AstraZeneca Switzerland, AZ

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Novartis

Alternative Name(s)

Novartis AG, Novartis International AG

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Pfizer UK

Alternative Name(s)

Pfizer Ltd, Pfizer Limited

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

A. Menarini Industrie Farmaceutiche Riunite Srl (Italy)

Funder Name

Institut de Recherches Internationales Servier (France)

Funder Name

Roche

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

Roche Diagnostics AG (Switzerland)

Funder Name

Merck AG (Switzerland)

Funder Name

Please note that these unrestricted grants cover only a part of the study costs (total approx 33%). The financial contribution is not the same for all companies.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/01/2009		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/02/2013		Yes	No
Results article	results	01/06/2013		Yes	No
Results article	results	01/08/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	results	15/07/2015		Yes	No

Results article	results	01/10/2015	Yes	No
Results article	results	08/08/2016	Yes	No
Protocol article	protocol	01/05/2006	Yes	No
Other publications	post hoc analysis	13/05/2018	Yes	No