ISRCTN43596477 https://doi.org/10.1186/ISRCTN43596477

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

Submission date 12/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/09/2005	**Overall study status** Completed	
Last Edited 14/06/2018	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/12/2002

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

Age group
Senior

Sex
Both

Target number of participants
820

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)

Sponsor details
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Sponsor type
University/education

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.

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

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?
Protocol article	protocol	01/05/2006		Yes	No
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
Other publications	post hoc analysis	13/05/2018		Yes	No