

Telmisartan randomised assessment study in ACE intolerant subjects with cardiovascular disease

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| Submission date 18/12/2002 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/12/2002 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 21/03/2016 | 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

ClinicalTrials.gov (NCT)
NCT00153101

Study information

Scientific Title

Telmisartan Randomised Assessment Study in ACE Intolerant Subjects with Cardiovascular Disease

Acronym

TRANSCEND

Study objectives

This parallel trial to ISRCTN16228603 (ONgoing Telmisartan Alone or in combination with Ramipril Global Endpoint Trial = ONTARGET) is to determine in angiotensin converting enzyme inhibitor (ACE-I) intolerant patients if telmisartan 80 mg daily is superior to placebo in reducing the composite endpoint of cardiovascular death, myocardial infarction (MI), stroke or hospitalisation for congestive heart failure (CHF).

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

Telmisartan (an angiotensin II blocker) or matched placebo.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Telmisartan

Primary outcome(s)

1. Cardiovascular death
2. Non-fatal myocardial infarction
3. Non-fatal stroke
4. Hospitalisation for congestive heart failure

Key secondary outcome(s)

1. Newly diagnosed congestive heart failure
2. Cardiovascular revascularisation procedures
3. Newly diagnosed diabetes
4. Cognitive decline (adjudication will be done by a special committee)
5. New onset of atrial fibrillation
6. Nephropathy

Completion date

01/01/2008

Eligibility**Key inclusion criteria**

1. Adults greater than or equal to 55 years
2. With a history of symptomatic coronary artery disease, cerebrovascular disease, peripheral vascular disease, or diabetes mellitus
3. Without proteinuria
4. Who are intolerant of ACE inhibitors

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not comply with the above criteria

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

United Kingdom

Australia

Austria

Belgium
Canada
China
Czech Republic
Denmark
Finland
France
Germany
Greece
Hong Kong
Hungary
Ireland
Italy
Korea, South
Malaysia
Mexico
Netherlands
New Zealand
Norway
Philippines
Poland
Portugal
Puerto Rico
Russian Federation
Singapore
Slovakia

South Africa

Spain

Sweden

Switzerland

Taiwan

Thailand

Türkiye

Ukraine

United Arab Emirates

United States of America

Study participating centre
Hamilton General Hospital
Hamilton
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Ontario L8L 2X2

Sponsor information

Organisation

Boehringer Ingelheim (Canada) Ltd

ROR

<https://ror.org/031sxcg258>

Funder(s)

Funder type

Industry

Funder Name

Boehringer Ingelheim (Canada) Ltd

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 | 20/03/2007 | | Yes | No |
| Results article | results | 27/09/2008 | | Yes | No |
| Results article | results | 06/10/2009 | | Yes | No |
| Results article | results | 30/03/2010 | | Yes | No |
| Protocol article | protocol | 01/07/2004 | | Yes | No |
| Basic results | | | | No | No |
| Other publications | baseline data | 01/04/2005 | | Yes | No |