

Telmisartan randomised assessment study in ACE intolerant subjects with cardiovascular disease

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

Contact name
Dr Salim Yusuf

Contact details
Population Health Research Institute
McMaster University
Hamilton General Hospital
McMaster Clinic
237 Barton St E
Hamilton
Canada
Ontario L8L 2X2
+1 (0)905 527 4322 ext 44515
yusufs@mcmaster.ca

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00153101

Protocol serial number
N/A

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
Canada
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