ISRCTN75807641 https://doi.org/10.1186/ISRCTN75807641

Telmisartan randomised assessment study in ACE intolerant subjects with cardiovascular disease

Submission date 18/12/2002	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/12/2002	**Overall study status** Completed	
Last Edited 21/03/2016	**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

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 infacrtion (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

Primary study design
Interventional

Study design
Randomised controlled trial

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/031sxg258

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