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Ongoing telmisartan alone or in combination with ramipril global endpoint trial

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

ONgoing Telmisartan Alone or in combination with Ramipril Global Endpoint Trial

Acronym
ONTARGET

Study objectives
To determine if:
1. Telmisartan (Micardis) 80 mg daily and Ramipril (Delix protect) 10 mg daily combination therapy is more effective in reducing the composite endpoint of Cardiovascular (CV) death, Myocardial Infarction (MI), stroke or hospitalisation for Congestive Heart Failure (CHF) compared with Ramipril 10 mg alone; and
2. Telmisartan 80 mg daily is at least as effective as (i.e. not less effective than) Ramipril 10 mg daily

A parallel trial "Telmisartan Randomised Assessment Study in Ace Intolerant Subjects with Cardiovascular Disease (TRANSCEND)" is registered with ISRCTN75807641.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Prevention randomised double-blind active-controlled parallel assignment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Congestive heart failure

Interventions
Ramipril (an ACE inhibitor), telmisartan (an angiotensin II blocker), their combination, or matched placebos.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Telmisartan, ramipril

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
30/09/2008

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. Coronary Artery Disease: previous MI (greater than 2 days prior to informed consent), or stable or previous unstable angina (greater than 30 days prior to informed consent) with documented multivessel coronary artery disease or a positive stress test, or multivessel Percutaneous Transluminal Coronary Angioplasty (PTCA) (greater than 30 days prior to informed consent), or previous multivessel Coronary Artery Bypass Graft (CABG) without angina (if surgery performed greater than 4 years prior to informed consent) or with recurrent angina after surgery
4. No definite and specific indication or contraindication for any of the study treatments
5. Written informed consent

Other High Risk:
6. Peripheral Arterial Disease: previous limb bypass surgery or angioplasty or amputation, intermittent claudication on history with ankle/arm Blood Pressure (BP) ratio less than 0.8 on at least one side, or significant stenosis by angiography or non-invasive testing
7. Previous stroke
8. Transient Ischaemic Attach (TIA) greater than 7 days and less than 1 year prior to informed consent
9. Diabetes Mellitus (types I or II): with evidence of end-organ damage (retinopathy, Left Ventricular Hypertrophy [LVH], micro- or macro-albuminuria), or any evidence of previous cardiac or vascular disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/01/2003

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

Austria

Belgium

Brazil

Canada

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
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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	10/04/2008		Yes	No
Results article	results	16/08/2008		Yes	No
Results article	results	06/10/2009		Yes	No
Results article	results	30/03/2010		Yes	No
Results article	results	01/03/2014		Yes	No
Protocol article	protocol	01/07/2004		Yes	No
Basic results				No	No
Other publications	baseline data	01/04/2005		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes