

Ongoing telmisartan alone or in combination with ramipril global endpoint trial

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

Study website

<http://www.ontarget-micardis.com/>

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00153101

Secondary identifying numbers

N/A

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

Study design

Prevention randomised double-blind active-controlled parallel assignment

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2003

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 Attack (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

Age group

Adult

Sex

Both

Target number of participants

31546

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

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 Kingdom

United States of America

Study participating centre
Hamilton General Hospital
Hamilton
Canada
Ontario L8L 2X2

Sponsor information

Organisation

Boehringer Ingelheim (Canada) Ltd

Sponsor details

Research and Development
2100 Cunard Street
Laval (Québec)
Canada
H7S 2G5
+1 450 682 4640
info@lav.boehringer-ingelheim.com

Sponsor type

Industry

Website

<http://www.boehringer-ingelheim.ca/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Boehringer Ingelheim (Canada) Ltd

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?
Basic results				No	No
Protocol article	protocol	01/07/2004		Yes	No
Other publications	baseline data	01/04/2005		Yes	No
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