# Telmisartan randomised assessment study in ACE intolerant subjects with cardiovascular disease

| Submission date           | <b>Recruitment status</b><br>No longer recruiting | [X] Prospectively regis  |
|---------------------------|---|--------------------------|
| 18/12/2002                |   | [X] Protocol             |
| Registration date         | Overall study status                              | [] Statistical analysis  |
| 18/12/2002                | Completed   | [X] Results              |
| Last Edited<br>21/03/2016 | Condition category<br>Circulatory System          | [_] Individual participa |

## Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s) Scientific

Contact name Dr Salim Yusuf

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

istered

plan

ant data

Secondary identifying numbers 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 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

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled 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

Telmisartan (an angiotensin II blocker) or matched placebo.

### Intervention Type

Drug

**Phase** Not Applicable

#### Drug/device/biological/vaccine name(s)

Telmisartan

#### 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

01/01/2004

### **Completion date**

01/01/2008

# Eligibility

### Key inclusion criteria

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

**Participant type(s)** Patient

**Age group** Adult

**Sex** Both

Target number of participants

6000

**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** 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 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 (0)450 682 4640 info@lav.boehringer-ingelheim.com

**Sponsor type** Industry

Website http://www.boehringer-ingelheim.ca/

ROR https://ror.org/031sxg258

# 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 Basic results Details

Date created

Date added

Peer reviewed? No Patient-facing? 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       | 27/09/2008 | Yes | No |
| Results article    | results       | 06/10/2009 | Yes | No |
| Results article    | results       | 30/03/2010 | Yes | No |