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Evaluation of World Health Organisation (WHO) cardiovascular disease (CVD)-risk management package - scenario one (Sri Lanka)

Submission date 06/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/06/2005	**Overall study status** Completed	
Last Edited 26/03/2008	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPC050

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
20 primary health care facilities.
10 facilities to apply the study protocol based on Scenario One of the WHO CVD-Risk Management Package (intervention sites).
Other 10 to continue with conventional treatment or usual care (control sites).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date
07/05/2004

Completion date
07/05/2005

Eligibility

Key inclusion criteria
1. Age 30 - 70 years
2. Currently not under treatment for hypertension
3. Systolic blood pressure between 140 and 179 mmHg measured twice with a 5 to 10 minute interval
4. Informed consent given

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Pregnancy
2. Trauma (injury) as presenting complaint
3. Renal diseases: nephropathy, renal artery stenosis
4. Endocrinological (hormonal) disorders: phaechromocytoma, Cushing syndrome, Conn syndrome, acromegaly
5. Coarctation of the aorta
6. Use of steroids and/or non-steroidal anti-inflammatories (NSAIs)
7. All acute conditions presenting with bleeding, pain, diarrhoea, vomiting, breathing disorders and circulatory disorders
8. Inability to comply with the follow-up requirements
9. Inability to provide informed consent

Date of first enrolment
07/05/2004

Date of final enrolment
07/05/2005

Locations

Countries of recruitment
Sri Lanka

Switzerland

Study participating centre
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Cardiovascular Diseases (CVD)/World Health Organization (WHO) (Switzerland)

Sponsor details
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Cardiovascular Diseases (CVD)/World Health Organization (WHO) (Switzerland)

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