

Nebivolol or Metoprolol in Arterial Occlusive Disease

Submission date 08/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-003583-31

Protocol serial number
BCBe/05/Neb-Pao/088

Study information

Scientific Title
Nebivolol or Metoprolol in Arterial Occlusive Disease: A double-blind, randomised controlled trial

Acronym

NORMA

Study objectives

To assess the effects of nebivolol compared to metoprolol on endothelial function by means of flow mediated dilation

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local research ethics board approved on the 23rd of February 2006 (ref: 837.025.06[5123])

Primary study design

Interventional

Study design

Double blind randomised active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peripheral arterial occlusive disease

Interventions

Patients randomised to receive either:

1. Nebivolol (Nebilet 5mg po once daily)
2. Metoprolol (Metoprolol succ. 95mg po once daily)

Total duration 52 weeks for all arms.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Nebivolol, metoprolol

Primary outcome(s)

Flow mediated dilation

All outcomes were measured at screening, baseline and the end of the intervention period (52 weeks).

Key secondary outcome(s)

1. Walking distance
2. Ankle brachial index
3. Systolic and diastolic blood pressure
4. Quality of Life

5. Laboratory parameters

6. Cludation Scale (CLAU-S) questionnaire

All outcomes were measured at screening, baseline and the end of the intervention period (52 weeks).

Completion date

01/04/2010

Eligibility

Key inclusion criteria

1. Male patients 30 years to 80 years or female postmenopausal patients up to 80 years
2. Arterial occlusive disease Fontaine 's stage II A or B
3. Stage I hypertension according to Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC) with or without hypertensive treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Arterial occlusive disease with rest pain or leg ulcer
2. Any concomitant disease limiting the exercise capacity of the patient
3. Poorly controlled diabetes HbA1c > 10%
4. Acute myocardial infarction during the last 6 month
5. Treatment with COX-2 inhibitors
6. Previous treatment with nebivolol or carvedilol
7. Concomitant treatment with drugs that may influence endothelial function
8. Contraindication to the study drug
9. Participation in an other clinical trail the last 6 month
10. Acute pathologic haemorrhage
11. Known hyperthyoidism
12. Psychiatric diseases
13. Known hypersensitivity to nebivolol or metoprolol
14. Prior or active malignancy in the previous 5 years
15. History of drug or alcohol abuse
16. Unwilling or unable to provide informed consent

Date of first enrolment

01/02/2006

Date of final enrolment

01/04/2010

Locations

Countries of recruitment

Germany

Study participating centre

II. Med. Klinik; Angiologie

Mainz

Germany

55131

Sponsor information

Organisation

Berlin-Chemie (Germany) (part of Menarini Group [Italy])

ROR

<https://ror.org/05gja4j15>

Funder(s)

Funder type

Industry

Funder Name

Berlin-Chemie (Germany) (part of Menarini Group [Italy])

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?
Basic results			16/05/2019	No	No

