# Nebivolol or Metoprolol in Arterial Occlusive Disease

| Submission date   | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|---|--|--|--|
| 08/06/2010        |   | ☐ Protocol                                 |  |  |
| Registration date | Overall study status                    | Statistical analysis plan                  |  |  |
| 24/06/2010        | Completed                               | [X] Results                                |  |  |
| Last Edited       | Condition category                      | [] Individual participant data             |  |  |
| 16/05/2019        | Circulatory System                      |  |  |  |

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Mr Gerhard Weisser

#### Contact details

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### Additional identifiers

EudraCT/CTIS number 2005-003583-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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])

### Study design

Double blind randomised active controlled parallel group 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 contact details below to request a patient information sheet

### 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**

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

Nebivolol, metoprolol

### Primary outcome measure

Flow mediated dilation

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

### Secondary outcome measures

- 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).

### Overall study start date

01/02/2006

### 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

#### Age group

Adult

### Sex

Both

### Target number of participants

128

#### 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 hypersensivity 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])

### Sponsor details

Glienicker Weg 125 Berlin Germany 12489

### Sponsor type

Industry

#### **ROR**

### Funder(s)

### Funder type

Industry

### Funder Name

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

### **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 |         |              | 16/05/2019 | No             | No              |