# Nebivolol or Metoprolol in Arterial Occlusive Disease

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
08/06/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/06/2010	Completed	[X] Results
<b>Last Edited</b> 16/05/2019	Condition category Circulatory System	[] Individual participant data
10/03/2019	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

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

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])

## Study design

Double blind randomised active controlled parallel group trial

## Primary study design

Interventional

## 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 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

# 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**