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Nebivolol or Metoprolol in Arterial Occlusive Disease

Submission date 08/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/06/2010	**Overall study status** Completed	
Last Edited 16/05/2019	**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
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

Phase III

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

https://ror.org/05gja4j15

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