TElmisartan 80 mg plus AMlodipine 10 mg fixed-dose combination tablet STudy versus Amlodipine 10 mg over encapsulated tablets as first line therapy in patients with Type 2 Diabetes Mellitus and Stage 1 or 2 hypertension: a phase III, eight week, randomised, double-blind, double-dummy, forced titration comparison - a ABPM substudy

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This study investigates whether the fixed-dose combination of telmsartan 80 plus amlodipine 5 or 10 is superior as a first line treatment to amlodipine 5 or 10 mg monotherapy of lowering mean sitting systolisch blood pressure in patients with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33529

Source
ToetsingOnline

Brief title
TEAMSTAT2DM - ABPM substudy

Condition

- Other condition

Synonym
high blood pressure, hypertension

Health condition

cardiovasculair, hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim BV.

Intervention

Keyword: efficacy, fixed-dose combination, stage 1 or 2 hypertension, type 2 diabetes mellitus

Outcome measures

Primary outcome

Primary endpoint:

the change from baseline in the mean seated trough cuff SBP following eight

weeks of treatment

Secondary outcome

Secundary endoints:

1. Key secundary endpoints

change from baseling in the mean seated trough cuff SBP following four and six

weeks of treatment (T80/A10 verus A10) and following one and two weeks of

treatment (T80/A5 versus A5)

2. Other secundary endpoints:

- change from baseling in mean seated trough cuff DBP after one, two, four, six and eight weeks of treatment

- response variables after one, two, four, six and eight weeks of treatment

DBP control (mean seated DBP<80 mmHg)

BP control (mean seated SBP<130 mmHg and mean seated DBP<80 mmHg)

DBP response (mean seated DBP<80 mmHg or a reduction of >=10 mmHg)

SBP response (mean seated SBP<130 mmHg or a reduction of >=10 mmHg)

BP normal (optimal: SBP<120 mmHg and DBP<80 mmHg)

(normal: SBP>=120 mmHg and <130 mmHg and DBP>=80 mmHg and <85 mmHg)

(high normal: SBP>=130 mmHg and <140 mmHg and DBP>=85 mmHg and <90 mmHg)

(high: SBP>=140 mmHg or DBP>=90 mmHg)

- change from baseline in urine albumin:creatinine ratio (UACR; measured in spot urine) after eight weeks of treatment

Safety endpoints

- adverse events

- changes from baseline in pulse rate

- changes in laboratory parameters

- ECG changes

- incidence of peripheral oedema

- orthostatic changes in SBP and DBP (calculated for both SBP and DBP as the mean seated BP at a particular visit substracted from the first standing BP at

the same visit)

Study description

Background summary

Title study
Telmisartan 80 mg plus amlodipine 10 mg fixed-dose combination tablet study versus amlodipine 10 mg over-encapsulated tablets as first line therapy in patients with type 2 diabetes mellitus and stage 1 or 2 hypertension: a phase III, eight week, randomised, double-blind, double-dummy, forced titration comparison.

New European guideline (European Society of Hypertension and Cardiology) acknowledge the need for an aggresive treatment of hypertension. This is based on the relation of hypertension and cardiovasculare morbidity and mortality. Diabetes mellitus is a big and growing health problem. Hypertension occurs in over half of these patients. Early treatment of hypertension in this patient group can delay the occurence of complications and therefore improve prognosis. Independantly hypertension and diabetes mellitus predispose to renal and cardiovascular problems. When those diseases occur together they exacerbate the risk of those complications. Therefore it is important in this patientpopulation to have even more strict guidelines for hypertension: <130/80 mmHg to lower the complication risk.
Large studies have shown that the majority of patients won't achieve there bloodpressure goal by treatment with one medicine. Adding a second therapy from a different treatment group is an option when the bloodpressure goal is not met. An alternative strategy is starting a fixed-dose combination or starting treatment with two types of medicine from the start fo treatment. This study tries to establish if this strategy is effective and safe.

Study objective

This study investigates whether the fixed-dose combination of telmsartan 80 plus amlodipine 5 or 10 is superior as a first line treatment to amlodipine 5 or 10 mg monotherapy of lowering mean sitting systolisch blood pressure in patients with diabetes mellitus type 2 and stage 1 or 2 hyeprtension.
Effectiveness of telmisartan 80 plus amlodipine 10 mg (T80/A10) versus amlodipine 10 mg (A10) is studied after 4,6 and 8 weeks of treatment as well as the effectiveness of telmisartan 80 mg plus amlodipine 5 mg (T80/A5) versus amlodipine 5 mg (A5) after 1 and 2 weeks of treatment.

Study design

This study compares the effectiveness and safety of 2 different treatment strategies:

1. the fixed-dose combination of telmisartan 80 mg and amlodipine 5 mg after 2 weeks forced titrated to telmisartan 80 mg and amlodipine 10 mg, or
2. amlodipine 5 mg, after 2 weeks forced titrated to amlodipine 10 mg

The study lasts for about 8 to 9 weeks. During the study there are 8 visites for the patient to the physician. The study starts with a screeningperiod of maximal 7 days. This screeningperiod is used to check whether the patient is eligible for participation in the study. After the screeningperiod the run-in period. Every patient receives placebo treatment during 2 to 3 weeks to achieve a washout of all stopped hypertensive medication.

If the systolisch bloodpressure after this run-in period is over 150 mmHg the patient is randomised to one of both treatment groupw. After 1 and 2 weeks the patient returns for bloodpressure measurmentens and the medication is forced titrated. After 4, 6 and 8 weeks after randomisation bloodpressure measurements will be repeated during the usage of the higher dose of medication.

During the last visit the physician will discuss the hypertension treatment of the patient after the study.

Intervention

Patients take their studydrug once daily. After a placebo run-in period the patients will be randomised to one of two treatment strategies:

1. fixed-dose combination of telmisartan 80 mg and amlodipine 5 mg, after 2 weeks forced titrated to telmisartan 80 mg and amlodipine 10 mg, or
2. amlodipine 5 mg, after 2 weeks forced titrated to amlodipine 10 mg.

Study burden and risks

One time physical examination
Two times ECG
Maximal three times laboratory (depending whether the patients gets randomised)
In females maximal three times a urine pregnancy test will be performed (depending whether the patients gets randomised)
At every visit blood pressure will be measured sitting and at the end of the treatment also standing one time.

Contacts

Public
Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL
Scientific
Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Baseline mean seated systolic blood pressure >150 mmHg; diagnosis of type 2 diabetes mellitus; age = >18; ability to stop current antihypertensive therapy without unacceptable risk to the patient and ability to provide written informed consent.

Exclusion criteria

Pre-menopausal women who are not pregnant, nursing, surgically sterile or practicing approved birth control; night shift workers; mean seated systolic =>180 and/or diastolic >=120 mmHg; type 1 diabetes mellitus; renal dysfunttion defined by laboratory parameters; functional class III-IV CHF; sensitivity to study drugs; concomitant medication known to affect blood pressure and unstable diabetes defined by HbA1c >10%

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2009
Enrollment:	78
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	micardis 40 and 80 mg
Generic name:	telmisartan 40 and 80 mg
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	norvasc 5 and 10 mg
Generic name:	amlodipine 5 and 10 mg
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	27-10-2008
Application type:	First submission

Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	19-11-2008
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	16-07-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	24-07-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	11-11-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	13-11-2009
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-000874-19-NL
CCMO	NL23348.040.08
Other	NTC-nummer nog niet bekend