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MEDINA: Metabolic syndrome, diabetes mellitus and renal protection

Submission date	Recruitment status	[ ] Prospectively registered
13/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LF2008/01, version 1.0, date: 22.06.2008

Study information

Scientific Title
MEDINA: Metabolic syndrome, diabetes mellitus and renal protection: an open label, randomised, controlled, parallel group trial

Acronym
MEDINA (metabolický syndrom, diabetes mellitus a nefroprotektivita)

Study objectives
The objective of this study is to find the optimal strategy of metabolic syndrome treatment, or diabetes mellitus and hypertension respectively.
The basic questions are:
1. Does the treatment initiation with Angiotensin-Converting Enzyme Inhibitor have advantages over treatment initiation with Angiotensin II Antagonist ?
2. Which second drug should be used in combination? Diuretics or calcium antagonist?
3. How is the risk lowered by simultaneous administration of statin?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentric Ethics Committee, University Hospital Brno Bohunice approved.

Primary study design
Interventional

Study design
Multicentre open label randomised active controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metabolic syndrome; diabetes mellitus; hypertension

Interventions
Patients randomised to receive:
1. Angiotensin II Antagonist (Angiotensin receptor blocker [ARB])
1.1. Baseline visit:
Patients with blood pressure ≥ 130/85mmHg will receive either Losartan (50mg) or Valsartan (80mg)
1.2. Visit 1 at 1 month:
In addition to Losartan (50mg) or Valsartan (80mg), patients with blood pressure ≥ 130/85mmHg will receive either Hydrochlorothiazide (12.5-25mg) or Amlodipine (5mg)
1.3. Visit 2 at 3 months:
Patients with blood pressure ≥ 130/85mmHg will receive an increased dose of either Losartan (100mg) or Valsartan (160mg) and either Hydrochlorothiazide (12.5-25mg) or Amlodipine (5mg)
1.4. Visit 3 at 6 months:
Patients with blood pressure ≥ 130/85mmHg will receive either Losartan (100mg) or Valsartan (160mg) and both Hydrochlorothiazide (12.5-25mg) and Amlodipine (5mg)
1.5. Visit 4 at 9 months:
Patients with blood pressure ≥ 130/85mmHg will receive either Losartan (100mg) or Valsartan (160mg), Hydrochlorothiazide (12.5-25mg) and an increased dose of Amlodipine (10mg)

2. Angiotensin-Converting Enzyme (ACE) Inhibitor
2.1. Baseline visit:

Patients with blood pressure ≥ 130/85mmHg will receive either Ramipril (5mg) or Perindopril (4mg)
2.2. Visit 1 at 1 month:
In addition to Ramipril (5mg) or Perindopril (4mg), patients with blood pressure ≥ 130/85mmHg will receive either Hydrochlorothiazide (5-25mg) or Amlodipine (5mg)
2.3. Visit 2 at 3 months:
Patients with blood pressure ≥ 130/85mmHg will receive an increased dose of either Ramipril (10mg) or Perindopril (8mg) and either Hydrochlorothiazide (12.5-25mg) or Amlodipine (5mg)
2.4. Visit 3 at 6 months:
Patients with blood pressure ≥ 130/85mmHg will receive either Ramipril (10mg) or Perindopril (8mg) and both Hydrochlorothiazide (12.5-25mg) and Amlodipine (5mg)
2.5. Visit 4 at 9 months:
Patients with blood pressure ≥ 130/85mmHg will receive either Ramipril (10mg) or Perindopril (8mg), Hydrochlorothiazide (12.5-25mg) and an increased dose of Amlodipine (10mg)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Losartan, valsartan, ramipril, perindopril, amlodipine, hydrochlorothiazide

Primary outcome(s)
1. Waist measurement, measured at baseline, 6 and 12 months
2. Blood samples for metabolic syndrome, DM and renal functions assessment, measured at baseline, 6 and 12 months
2.1. glycine
2.2. cholesterol measured additionally at 3 months and electively at 9 months
2.2.1. High Density Lipoprotein (HDL)
2.2.2. Low density Lipoprotein (LDL)
2.2.3. total cholesterol
2.3. triglycerides (TG)
2.4. uric acid
2.5. urea
2.6. creatinine
2.7. glycated haemoglobin
2.8. complete blood count
3. Blood pressure measurement at baseline. 6, 12 and 18 months
4. Microalbuminuria, paper measurement at baseline, 6 and 12 months

Primary objective is to lower the absolute risk evaluated by Symptoms, Causes, Outcomes, Resources and Effects (SCORE) as well as to increase the number of patients with SCORE level below 5%. SCORE is an estimation of cardiovascular accident risk in next 10 years, calculated from data as: age, sex, systolic blood pressure, cholesterol level, history of smoking and diabetes mellitus.

Key secondary outcome(s)
1. Percentage of patients with blood pressure < 140/90 mmHg
2. Percentage of patients with cholesterol < 5,0 mmol/l

3. Percentage of patients not complying with the criteria for metabolic syndrome
4. Renal function evaluated as glomerular filtration and microalbuminuria
5. Variation in glycated hemoglobin

Completion date
30/05/2011

Eligibility

Key inclusion criteria
1. Diabetes mellitus type II with primary hypertension (systolic pressure > 130 mmHg or diastolic pressure > 85 mmHg)
2. Two criteria of metabolic syndrome
3. Age > 40
4. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Myocardial infarction, stroke, Percutaneous Transluminal Coronary Angioplasty (PTCA), Coronary Artery Bypass Graft (CABG) in the last 3 months
2. Secondary hypertension
3. Clinically apparent heart failure
4. Diabetes mellitus type I
5. Comorbidity with bad prognosis (death expectation > 30%)
6. Gravidity and fertile women without sufficient contraception

Date of first enrolment
20/11/2008

Date of final enrolment
30/05/2011

Locations

Countries of recruitment
Czech Republic

Study participating centre
Interní kardiologická klinika
Brno
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Sponsor information

Organisation
DSC Services, s.r.o. (Czech Republic)

ROR
https://ror.org/04sw4ge25

Funder(s)

Funder type
Industry

Funder Name
DSC Services, s.r.o. (Czech Republic)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration