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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

**Contact name**
Prof Jindøich pinar

**Contact details**
Interní kardiologická klinika
Fakultní nemocnice Brno
Jihlavská 20
Brno
Czech Republic
62500
+42 (0)53 2232601
jspinar@fnbrno.cz

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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.

## Study design
Multicentre open label 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

## 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
20/11/2008

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
2000

### 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
Czech Republic
62500

## Sponsor information

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

### Sponsor details
Brnìnská 800
Tinov
Czech Republic
666 03
+42 (0)77 7826208
chroust@dscservices.cz

### Sponsor type
Industry

### Website
http://www.dscservices.cz/index-en.php

### ROR
https://ror.org/04sw4ge25

# Funder(s)

**Funder type**
Industry

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

# 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