ISRCTN41655008 https://doi.org/10.1186/ISRCTN41655008

# Comparison of effects of combined angiotensin converting enzyme inhibitor and low dose thiazide diuretic on insulin action in patients with hypertension and type two diabetes: a double-blind crossover study

**Submission date**
19/12/2006

**Recruitment status**
No longer recruiting

**Registration date**
06/02/2007

**Overall study status**
Completed

**Last Edited**
03/05/2011

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Patrick Bell

**Contact details**
Regional Centre for Endocrinology
Level One
Royal Victoria Hospital
Belfast
United Kingdom
BT12 6BA
patrick.bell@royalhospitals.n-i.nhs.uk

## Additional identifiers

**Protocol serial number**
203/01

# Study information

## Scientific Title

## Study objectives
New blood pressure targets have resulted in increased use of antihypertensive drugs including combinations. This study aimed to establish the safety in terms of insulin sensitivity of a low dose thiazide (bendroflumethiazide 1.25 mg)/Angiotensin Converting Enzyme (ACE) inhibitor combination.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Research Ethics Committee, Royal Victoria Hospital on behalf of Queens University Belfast on 22 /082001(ref: 203/01)

## Study design
Randomised double-blind crossover study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Type two diabetes and essential hypertension

## Interventions
Patients were commenced on captopril 50 mg twice daily and this continued throughout the trial. Patients were randomly assigned to either bendroflumethiazide 1.25 mg once daily or placebo for twelve weeks before being crossed over to receive the alternate randomly allocated bendroflumethiazide or placebo. Insulin action was assessed at the end of the placebo run-in and at the end of the two treatment periods using an isoglycaemic hyperinsulinameic clamp technique.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Captopril and bendroflumethiazide

## Primary outcome(s)
When compared to captopril alone, treatment with low dose bendroflumethiaizide (1.25 mg) in combination with captopril produced a 23% reduction in glucose infusion rates required to

maintain isoglycaemia and there was a comparable reduction in isotopically induced decline in peripheral insulin sensitivity most probably in skeletal muscle. The combination of low-dose bendroflumethiazide 1.25 mg and captopril resulted in a significant reduction in blood pressure (6/3 mmHg) compared to captopril alone.

### Key secondary outcome(s))
Serum potassium was significantly lower after treatment with captopril and bendroflumethiaizide as compared to treatment with captopril alone.

### Completion date
01/04/2004

## Eligibility

### Key inclusion criteria
1. Aged 40 to 65 years
2. Hypertension (either newly diagnosed or controlled on treatment)
3. Type two diabetes established on dietary treatment with or without oral hypoglycaemic agents
4. Fasting plasma glucose in the range 7 - 12 mmol/l

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Not Specified

### Key exclusion criteria
1. Secondary hypertension
2. Hepatic or renal disease or were taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or steroids which may affect insulin action

### Date of first enrolment
01/08/2001

### Date of final enrolment
01/04/2004

## Locations

### Countries of recruitment
United Kingdom

Northern Ireland

**Study participating centre**
**Regional Centre for Endocrinology**
Belfast
United Kingdom
BT12 6BA

# Sponsor information

**Organisation**
Royal Victoria Hospital (UK)

**ROR**
https://ror.org/03rq50d77

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Metabolic Research fund - Royal Victoria Hospital, Belfast, N.Ireland (UK)

**Funder Name**
Royal Fellowship - Royal Victoria Hospital (UK)

# Results and Publications

**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? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2008 | | Yes | No |