

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	<input type="checkbox"/> Prospectively registered
Registration date 06/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 hyperinsulinaemic clamp technique.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Captopril and bendroflumethiazide

Primary outcome measure

When compared to captopril alone, treatment with low dose bendroflumethiazide (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.

Secondary outcome measures

Serum potassium was significantly lower after treatment with captopril and bendroflumethiazide as compared to treatment with captopril alone.

Overall study start date

01/08/2001

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

Age group

Adult

Sex

Not Specified

Target number of participants

15

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

Northern Ireland

United Kingdom

Study participating centre

Regional Centre for Endocrinology

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Royal Victoria Hospital (UK)

Sponsor details

c/o Professor Patrick Bell

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Sponsor type

Hospital/treatment centre

Website

<http://www.royalhospitals.org/>

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

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?
Results article	results	01/05/2008		Yes	No