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Clinical trial on the efficacy of an intervention package to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP

Submission date
17/06/2010

Recruitment status
No longer recruiting

Registration date
27/07/2010

Overall study status
Completed

Last Edited
13/01/2015

Condition category
Circulatory System

[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PS09/01456

Study information

Scientific Title
A randomised controlled trial on the efficacy of a multifactorial intervention to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP

Study objectives
Background:
Lowering blood pressure (BP) with antihypertensive drugs has an important risk reduction effect on cardiovascular events, mainly stroke and total mortality. However lack of adherence to antihypertensive medication reduces its effectiveness and increases the risk for adverse effects to the medication. Improvement of patient adherence to the treatment could be similar in relative risk reduction than the development of a new drug.

Hypotheses:
1. In primary care patients with poorly- or un-controlled BP and low adherence to treatment, a 9-month multifactorial intervention with the aim of improving communication between medical staff and patient and thus facilitating the taking of medication will result in decreased systolic blood pressure (SBP) at 12 months compared with patients in the control group
2. The estimated direct cost at 12 months resulting from the use of health services associated with hypertension in the intervention group will be at least 10% lower than the control group
3. The number needed to treat (NNT) will be 10 - 15

Please note that as of 16/01/2013, the following changes were made to the record:
1. The public title was previously "Clinical trial on the efficacy of an intervention package to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP and low adherence to treatment"
2. The scientific title was previously "A randomised controlled trial on the efficacy of a multifactorial intervention to improve adherence to treatment for systolic blood pressure (BP) reduction in primary care patients with poorly controlled or uncontrolled BP and low adherence to treatment"

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee on Human Reseach of Balearic Islands approved on the 26th May 2010

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Mr Alfonso Leiva Rus [aleiva@ibsalut.caib.es] to request a patient information sheet

Health condition(s) or problem(s) studied
Non-optimally controlled hypertension

Interventions
Patients in the intervention group will attend of 3 sessions consisting of a 30 minute semi-structured motivational interview and a 15-minute health education programme combined with simplifying dosing regimens, family and/or social support, blood pressure self-monitoring and use of medication reminders.

Patients in the control group will receive treatment as usual.

The duration of the intervention will be 6 months. The total duration of follow-up will be 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in systolic BP at 12 months

Secondary outcome measures
1. Change in diastolic BP
2. Proportion of participants with adequate BP control at 12 months
3. Total direct cost

Overall study start date
15/10/2010

Completion date
15/12/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/01/2013:
1. Patients between 18 and 80 years of age
2. Non controlled BP according to European Societies of Hypertension and Cardiology (ESH/ESC) guidelines (i.e. BP less than 140/90 mmHg or less than 130/80 mmHg in diabetic or renal failure patients)

Previous inclusion criteria until 16/01/2013:
1. Patients between 18 and 80 years of age
2. Non controlled BP according to European Societies of Hypertension and Cardiology (ESH/ESC) guidelines (i.e. BP less than 140/90 mmHg or less than 130/80 mmHg in diabetic or renal failure patients)
3. Adherence below 80% to AHT by Hayness-Sacket Test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
309 randomised patients from primary care centres in Spain

Key exclusion criteria
1. Non-essential hypertensive patients
2. Haemodialysis patients
3. Institutionalised patients

Date of first enrolment
15/10/2010

Date of final enrolment
15/12/2012

Locations

Countries of recruitment
Spain

Study participating centre
Gerencia de Atención Primaria
Palma de Mallorca
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07003

Sponsor information

Organisation
Health Service of the Balearic Islands (Servei de Salut de les Illes Balears [IB-salut]) (Spain)

Sponsor details
Mallorca Primary Care Management
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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

Funder Name
Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (Spain)

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	27/09/2010		Yes	No
Other publications	resulst	05/12/2014		Yes	No