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Antidepressant drug therapy vs a community-based psychosocial intervention for the treatment of moderate postnatal depression: a pragmatic randomised controlled trial

Submission date
16/09/2003

Recruitment status
No longer recruiting

Registration date
16/09/2003

Overall study status
Completed

Last Edited
08/08/2011

Condition category
Mental and Behavioural Disorders

[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

Contact name
Prof Deborah Sharp

Contact details
Academic Unit of primary care
University of Bristol
Bristol
United Kingdom
BS8 2AA
+44 (0)117 3313812
debbie.sharp@bris.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 02/07/04

Study information

Scientific Title

Acronym
RESPOND

Study objectives
The study proposes to compare the effectiveness and cost-effectiveness of antidepressant drug therapy versus a community-based psychosocial intervention (Health Visitor delivered non-directive counselling) in the treatment of moderate postnatal depression.

Protocol can be found at: http://www.hta.ac.uk/protocols/200200070004.pdf
More details can be found at: http://www.hta.ac.uk/1373

Please note that, as of 11 January 2008, the anticipated start and end dates of this trail have been updated from 1 March 2004 and 30 September 2007 to 1 June 2004 and 30 April 2008, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Two arm multi-centre pragmatic randomised controlled trial

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
Postnatal depression

Interventions

A two arm multi-centre pragmatic randomised controlled trial, with randomisation at the level of the individual woman. Women who reach the threshold for inclusion (EPDS>12, CIS-R>11) at 8 weeks will be randomised to either antidepressants or a 4 week waiting list for counselling. Women who do not respond to the allocated therapy in their group will be offered the opportunity to either switch or combined therapies after the primary outcome has been measured (4 weeks for antidepressants, 18 weeks for counselling) Thus the research design allows women to receive both antidepressants and psychological therapy is required.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Antidepressants

Primary outcome measure
The primary outcome measure is the EPDS at 4 weeks, 18 weeks and 44 weeks. In addition, the trial will use the SF-36 as a generic measure of functional quality of life, the EQ5D for economic analysis, the MAMA for parenting skills and attitudes towards the baby, the GRIMS for the quality of the marital relationship. The trial will ask partners to complete the GHQ12 the PAPA and the GRIMS. At 12 months we will assess the family milieu using the HOME and the child's development using the Bayley scales.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/06/2004

Completion date
30/04/2008

Eligibility

Key inclusion criteria
Women with post natal depression up to 3 months post natal

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/2004

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of primary care
Bristol
United Kingdom
BS8 2AA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
Sheila.Greener@doh.gsi.gov.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	01/09/2010		Yes	No
Results article	results	03/08/2011		Yes	No