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Maternal Acupuncture and Neonatal Abstinence Syndrome

Submission date	Recruitment status	[ ] Prospectively registered
09/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/07/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAM 05-325

Study information

Scientific Title

Study objectives
Infants whose mothers have been randomized to receive standard care (methadone maintenance) in combination with daily acupuncture treatments versus standard care alone will require fewer days of treatment with morphine for neonatal abstinence syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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
Drug addiction

Interventions
Acupuncture using National Acupuncture Detoxification Association (NADA) protocol + standard care versus standard care alone.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Days of neonatal morphine treatment

Secondary outcome measures

1. Gestational age at birth
2. Rates of intrauterine growth restriction
3. Scores on the Neonatal Abstinence Syndrome Scale
4. Rates of admission to a level II or level III nursery and length of stay
5. Days to regain birthweight
6. Rates of apprehension by the Ministry of Children and Families prior to discharge from hospital

Overall study start date
01/08/2005

Completion date
01/08/2007

Eligibility

Key inclusion criteria
All women admitted to the Chemical Dependency Unit at BC Womens Hospital will be offered participation.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
180

Key exclusion criteria
Women who can neither read nor write English.

Date of first enrolment
01/08/2005

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Canada

Study participating centre
University of British Columbia (UBC) Dept of Health Care and Epidemiology
Vancouver

Canada
V6T-1Z3

Sponsor information

Organisation
Toronto SickKids Foundation (Canada)

Sponsor details
555 University Avenue
Toronto
Canada
M5G-1X6

Sponsor type
Charity

Website
http://www.sickkids.ca

ROR
https://ror.org/04374qe70

Funder(s)

Funder type
Charity

Funder Name
Toronto Sickkids Foundation

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	23/12/2012		Yes	No