ISRCTN68305337 https://doi.org/10.1186/ISRCTN68305337

The efficacy of chiropractic spinal adjustments as a treatment protocol in the management of infantile colic: a randomised controlled trial

Submission date
29/01/2007

Recruitment status
No longer recruiting

Registration date
09/10/2007

Overall study status
Completed

Last Edited
10/10/2007

Condition category
Neonatal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives
Chiropractic manipulation is more effective than placebo for the treatment of infantile colic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Responsible Committee on Human Experimentation, and the Research Ethics Committee of Technikon Natal, Durban, South Africa. Approved in 1998.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infantile colic

Interventions
Chiropractic manipulation/mobilization for spinal adjustments vs placebo treatment. One hour per session, 6 sessions over a 2-week period with a follow-up consultation after 1 month.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Parental questionnaire at baseline, each subsequent treatment session and follow-up consultation. The questionnaire asked the following quetisons:
1. Measured from the parents' perception, how long does the baby cry with each attack of colic?
2. How often does the colic occur in 24 hours?
3. Does the colic attack occur at any particular time of day or night?
4. Does anything seem to precipitate an attack?
5. For how long does the baby sleep between colic attacks?
6. Does the baby still require medicine to relieve the colic?
7. How would you rate the baby's response to treatment (1-5)?
8. Has the baby had any other illnesses?

Key secondary outcome(s)
Increased joint motion assessed at baseline, each subsequent treatment session and follow-up consultation.

Completion date
01/12/1998

Eligibility

Key inclusion criteria
1. The infant was to undergo a thorough examination by the consulting paediatrician to determine the health of the infant and to exclude any underlying organic problem, thereby ensuring a strict diagnosis of infantile colic
2. The infant was to be 0 to 8 weeks of age at the commencement of treatment to exclude the possibility of spontaneous cessation of the colic at 3 months
3. Apart from the colic, the infant was to suffer from no other condition/disease
4. If any medication had been administered to the infant to relieve the symptomatology of colic prior to the commencement of treatment (whether prescribed or over-the-counter drugs) the infant was required to remain on the same medication for the duration of the study, if the medication was required
5. Written informed consent was to be obtained from a parent before participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Any participant that did not meet the inclusion criteria.

Date of first enrolment
01/01/1998

Date of final enrolment
01/12/1998

Locations

Countries of recruitment
Australia

South Africa

Study participating centre
Murdoch University
Murdoch
Australia
6150

Sponsor information

Organisation
Technikon Natal School of Chiropractic (South Africa)

ROR
https://ror.org/0303y7a51

Funder(s)

Funder type
University/education

Funder Name
Technikon Natal School of Chiropractic (South Africa)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration