

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/10/2007	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

N/A

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.

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

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 measure

Parental questionnaire at baseline, each subsequent treatment session and follow-up consultation. The questionnaire asked the following questions:

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?

Secondary outcome measures

Increased joint motion assessed at baseline, each subsequent treatment session and follow-up consultation.

Overall study start date

01/01/1998

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

Age group

Neonate

Sex

Both

Target number of participants

30

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)

Sponsor details

Durban University Of Technology - Durban Central Offices

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CharmaK@dut.ac.za

Sponsor type

University/education

Website

<http://www.dut.ac.za/front%20page.aspx>

ROR

<https://ror.org/0303y7a51>

Funder(s)

Funder type

University/education

Funder Name

Technikon Natal School of Chiropractic (South Africa)

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