

A study of the effects of Colief in infants with persistent abdominal colic

Submission date 09/03/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/03/2017	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Colic is excessive, frequent crying in a baby who appears to be otherwise healthy. It is known that 38% or more cases of infant colic are related to a temporary lack of the lactase enzyme, causing lactose (a sugar found in milk) to build up in the gut and then ferment. By providing lactase in the milk feed, the lactose will be digested. The aim of this study is to assess the effect of lactase (as the marketed product Colief) in the treatment of young babies who have colic.

Who can participate?

Babies between the ages of 21 and 90 days with abdominal colic

What does the study involve?

Participating babies are randomly allocated to have either lactase or a placebo (dummy drug) added to their formula milk feeds over two 10-day periods with a 4-day break in between. Improvement in colic symptoms is assessed by measuring crying time using a diary completed by the parent or guardian during the two treatment periods. Other than physical examination of the babies the study does not involve intervention of any kind (e.g. blood samples or X-rays).

What are the possible benefits and risks of participating?

Babies may benefit from relief of their abdominal colic if the symptoms are due to lactase deficiency. Parents/guardians may therefore benefit from reducing their anxiety levels and improving their sleep patterns. If the symptoms are reduced, the product (Colief®) is available for purchase. There are no other lactase products for infants demonstrated as effective and so without alternatives the infant would probably continue to have symptoms until lactase is produced naturally. The tested product is a nutritional supplement (natural biological product) added to the formula feeds in low doses and as such the foreseeable risks are negligible. The product has also been available on the market in many countries for many years.

Where is the study run from?

1. Springvale Medical Centre (UK)
2. Sandwell General Hospital (UK)
3. St Mary's Hospital (UK)
4. Miami Children's Hospital (USA)

5. New York Children's Hospital (USA)
6. Duke Children's Hospital (USA)
7. Chicago Lurie Children's Hospital (USA)
8. Kwong Wah Hospital (Hong Kong)
9. Prince of Wales Hospital (Hong Kong)
10. The Royal Children's Hospital Melbourne (Australia)

When is the study starting and how long is it expected to run for?
September 2016 to December 2017

Who is funding the study?
Crosscare Ltd (Ireland)

Who is the main contact?
Dr Michael Bowles

Contact information

Type(s)
Scientific

Contact name
Dr Michael Bowles

Contact details
MMI Ltd
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United Kingdom
WD6 1QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CCL-001

Study information

Scientific Title
Multinational, multicentre, randomized, placebo-controlled, double-blind, crossover study of lactase in infant subjects with symptoms of abdominal colic

Acronym

COLIIC

Study objectives

Colief will prove significantly better than placebo in reducing crying time in infants with infantile colic
with classically-defined infantile colic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Integrated Research Application System (IRAS) (UK) - pending
2. Kowloon Central Cluster Ethics Committee (Hong Kong) - pending
3. University of Melbourne Ethics Committee (Australia) - pending
4. Institutional Review Board (IRB) Children's Hospital Miami, Florida (USA) - pending

Study design

Multinational multicentre randomized placebo-controlled double-blind crossover study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Infantile abdominal colic

Interventions

Participants will be randomized to receive the following treatments over two 10-day periods with a 4-day washout period between treatments:

1. Lactase (Colief) treated milk feeds (4 drops of solution added to each formula feed)
2. Placebo (4 drops of matching placebo added to each formula feed)

Intervention Type

Supplement

Primary outcome measure

Crying time, measured in minutes from diary cards completed by parents/guardians over each 10-day treatment period

Secondary outcome measures

1. Fussing/fretting time
2. Stool frequency
3. Overall parent evaluation

Measured from the diary cards completed by parents/guardians during each 10-day treatment period

Overall study start date

01/09/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Male or female babies between the ages of 21 and 90 days inclusive at time of study entry
2. Born at a gestational age of at least 32 weeks and with a birth weight of at least 2000 g
3. Symptoms of abdominal colic for at least 3 hours per day for at least 3 days per week present over the preceding 2 weeks
4. Associated signs of spasm and/or lower limb flexure and/or diarrhoea
5. Otherwise healthy babies
6. Parents/guardians willing to consent to their baby participating in the study
7. Exclusively bottle-fed babies

Participant type(s)

Patient

Age group

Child

Lower age limit

21 Days

Upper age limit

90 Days

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Age <21 days or >90 days at date of study entry
2. Born at <32 weeks gestation or with birth weight <2000 g
3. Any significant congenital disorder
4. Any significant co-existing disease

5. Partially breast-fed
6. Receiving any other anti-colic medicines
7. Known intolerance to beta-galactosidase (lactase)

Date of first enrolment

01/04/2017

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

Australia

England

Hong Kong

United Kingdom

United States of America

Study participating centre

Melbourne Children's Hospital

Australia

Victoria 3052

Study participating centre

Kwong Wah Hospital

Hong Kong

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Study participating centre

Prince of Wales Hospital

Hong Kong

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Study participating centre

Burncross Surgery

United Kingdom

S35 1RN

Study participating centre
Sandwell General Hospital
United Kingdom
B71 4HJ

Study participating centre
Springvale Medical Centre
United Kingdom
YO21 1SD

Study participating centre
St Mary's Hospital, London
United Kingdom
W2 1NY

Study participating centre
Miami Children's Hospital
United States of America
FL 33155

Study participating centre
New York Children's Hospital
United States of America
NY 10032

Study participating centre
Duke Children's Hospital
United States of America
NC 27710

Study participating centre
Chicago Lurie Children's Hospital
United States of America
IL 60611

Sponsor information

Organisation

Crosscare Ltd

Sponsor details

The Herbert Building
The Park, Carrickmines
Dublin
Ireland
Dublin 18

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Crosscare Ltd

Results and Publications

Publication and dissemination plan

The plan is to publish as one main paper in a peer reviewed journal during the last quarter of 2018.

Intention to publish date

01/10/2018

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Data sharing statement to be made available at a later date