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

Submission date 09/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/03/2017	**Overall study status** Completed	
Last Edited 21/03/2017	**Condition category** Signs and Symptoms	

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
Devonshire House
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Borehamwood
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