ISRCTN12919460 https://doi.org/10.1186/ISRCTN12919460

Clinical study to evaluate the efficacy of probiotic product Bio-Kult Infantis as concomitant treatment of acute infectious diarrhoea in children

Submission date
13/07/2016

Recruitment status
No longer recruiting

Registration date
14/07/2016

Overall study status
Completed

Last Edited
12/01/2018

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Acute gastroenteritis (AGE) is a common condition which involves sudden inflammation (swelling) of the lining of the stomach due to a viral infection. It affects people of all ages, but is most common in young children. One of the main symptoms is diarrhoea, which if lasts for more than three days can be cause severe dehydration (loss of fluids). Probiotics are living microorganisms, which are thought to have a positive influence health. Among the most commonly used are lactic bacteria, as they are naturally present in the gut and help with digestion (so called “good bacteria”). Probiotics are mainly available as food additives, such as yogurts, or in supplements. Bio-Kult Infantis is an advanced, multi-strain formula for babies, toddlers and young children containing seven strains of live bacteria with addition of prebiotics, Omega-3 fatty acids and Vitamin D3. Previous studies have shown that it can be beneficial in the treatment of gastroenteritis symptoms and can help speed up diarrhoea recovery. This may be due to the probiotic replenishing the “good bacteria” lost as a result of the diarrhoea. The aim of the study is to investigate the effectiveness of Bio-Kult Infantis in the treatment of diarrhoea.

Who can participate?
Children aged between six months and six years that seek medical attention for AGE and receive rehydration therapy but do not have to stay in hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group eat the Bio-Kult Infantis product once a day for seven days. Participants in the second group eat a placebo (dummy) formula for seven days. For both groups, if there is no improvement within seven days, the researcher can extend the length of treatment to ten days. Parents of children in both groups are given a diary in which they are asked to record the number of diarrhoea episodes. Once week after the end of treatment, parents of children in both groups are telephoned in order to check when the diarrhoea stopped and to find out if there were any side effects from the formula.

What are the possible benefits and risks of participating?
Participants who receive the Bio-Kult Infantis may benefit from a faster recovery from their diarrhoea. Bio-Kult Infantis, has been on the market for some time and there have been no confirmed negative reactions reported in connection its use. Therefore, there are no predicted risks for children taking part.

Where is the study run from?
Three hospitals in Croatia and 20 hospitals in Slovenia.

When is the study starting and how long is it expected to run for?
September 2015 to March 2018

Who is funding the study?
Probiotics International Ltd. (Protexin) (UK)

Who is the main contact?
Mrs Mojca Fir

Contact information

Type(s)
Scientific

Contact name
Mrs Mojca Fir

Contact details
Vizera d.o.o.
Vojkova 4
Ljubljana
Slovenia
1000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BKI-01

Study information

Scientific Title
Randomized, 2 arm, parallel, double-blind, placebo-controlled clinical study to evaluate the efficacy of probiotic product Bio-Kult Infantis as adjuvant therapy in treatment of acute gastroenteritis in children

Acronym
Infantis

Study objectives
The aim of the study is to show the effectiveness of Bio-Kult Infantis as an adjuvant therapy in treating acute diarrhoea, compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Medical Ethics Comittee of Republic of Slovenia

Study design
Paediatric multi-centre randomized double-blind 2 arm parallel placebo-controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Acute gastroenteritis (AGE) with evidence of dehydration

Interventions
Participants are randomised to one of two study arms in a 1:1 ratio using envelope randomisation.

Treatment arm: Participants receive Bio-Kult Infantis (an advanced probiotic multi-strain formula for infants with addition of prebiotics, omega 3 and vitamin D3) once a day for seven days, with an option to prolong teatment to ten days if no improvement is observed. The prolongation of the treatment will be the decision of the Investigator.

Control arm: Participants receive a placebo (product without probiotic organisms, prebiotics, omega-3 or vitamin D3 containing 100% maltodextrin) once a day for seven days, with an option to prolong teatment to ten days if no improvement is observed. The prolongation of the treatment will be the decision of the Investigator.

A week after the last dose of study treatment (i.e. day 15), the follow-up phone call will be performed to check the overall status of the patient and check for eventual adverse events. The total duration of study per patient will be at least 15 days, and up to 18 days in case of the prolonged treatment.

Intervention Type
Supplement

Primary outcome measure
Duration of diarrhoea – “time to last diarrheal stool” is measured as the time in hours since the first time the Study Product is given until the last liquid/loose stool in the last 24 hours with at least three liquid/loose defecations.

Secondary outcome measures
Number of diarrheal episodes per day (frequency of defecation) is measured from patient diaries completed daily by the patient's caregiver throughout the study period.

Overall study start date
01/09/2015

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Patient Informed Consent (PIC) form signed by parent or legal guardian
2. Aged between 6 months and 6 years (up to the age of 5 years and 11 months) at the time of the signature of PIC
3. Confirmed acute diarrhoea according to WHO (at least 3 loose or watery stools within last 24h), which lasted less than 2 days (< 48 h) prior to signature of PIC
4. Diagnosed with acute gastroenteritis with evidence of dehydration (evaluated according to CDS) and in need of rehydration therapy (oral or IV)
5. Only patient treated in an out-patient setting (i.e. managed in an A+E department without subsequent hospitalization) is eligible; if it is decided that the patient needs to be hospitalized, he or she should not be included in the study

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
186

Key exclusion criteria
1. Patient diagnosed with gastroenteritis, but it is determined that they don’t need rehydration treatment (Score 0 according to CDS)
2. Patient who received antibiotic treatment within the last two months prior to onset of gastroenteritis
3. Patient who was taking probiotic supplements, dairy product with high bacterial count, such as Actimel or Yakult, or milk formula with probiotics, in the last month prior to onset of gastroenteritis (consumption of normal yoghurts is acceptable)
4. Patient who has to be hospitalized
5. Patient who is exclusively breastfed
6. Patient with diabetes
7. Immuno-compromised patient or patient with other severe chronic disorders that might influence the outcome of study therapy (as evaluated by Investigator)
8. Patient with oedema
9. Malnutrition (< 3% EBW; under the 3rd percentile of expected body weight)
10. Known lactose or gluten intolerance
11. Known allergy to cow’s milk proteins, fish, or any of the substances of the probiotic product or placebo
12. Patient who already participated and completed this study, and has repeated gastroenteritis while the enrolment into the study is still open
13. Patient participating in any other interventional clinical study
14. Patient with confirmed bacterial AGE and/or patient who need antibiotic treatment, will be excluded from the study

Date of first enrolment
15/07/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Croatia

Slovenia

Study participating centre
General Hospital Jesenice
Department of Paediatrics
Cesta maršala Tita 112

Jesenice
Slovenia
4270

Study participating centre
General Hospital Novo mesto
Department of Paediatrics
Šmihelska cesta 1
Novo mesto
Slovenia
8000

Study participating centre
University Medical Centre Ljubljana
Department of Paediatrics
Zaloška cesta 7
Ljubljana
Slovenia
1000

Study participating centre
University Hospital Centre Osijek
Department of Paediatrics
Joseph Huttlera 4
Osijek
Croatia
31000

Study participating centre
University Hospital Centre Rijeka
Department of Paediatrics
Krešimirova 42
Rijeka
Croatia
51000

Study participating centre
Hospital for Infectious Diseases "Dr Fran Mihaljevic"
Department of Paediatrics
Mirogojska 8
Zagreb

Croatia
10000

Study participating centre
Barsos-Mc, Zdravstvene Storitve d.o.o.
Gregorčičeva ulica 11
Ljubljana
Slovenia
1000

Study participating centre
Health Centre of dr. Julij Polc Kamnik
Novi trg 26
Kamnik
Slovenia
1241

Study participating centre
Health Centre Grosuplje
Pod gozdom c. I/14
Grosuplje
Slovenia
1290

Study participating centre
Health Centre Ivančna Gorica
Cesta 2. grupe odredov 16
Ivančna Gorica
Slovenia
1295

Study participating centre
Health Centre Trebnje
Goliev trg 3
Trebnje
Slovenia
8210

Study participating centre

Health Centre Novo mesto
Kandijska cesta 4
Novo mesto
Slovenia
8000

Study participating centre
Health Centre Krško
Cesta Krških žrtev 132 c
Krško
Slovenia
8270

Study participating centre
Health Centre Brežice
Černelčeva cesta 8
Brežice
Slovenia
8250

Study participating centre
Health Centre of dr. Franc Ambrožič
Prečna ulica 2
Postojna
Slovenia
6230

Study participating centre
Health Centre Koper
Dellavallejeva ulica 3
Koper
Slovenia
6000

Study participating centre
Dr. Daneu, d.o.o.
Cesta solinarjev 1
Portorož
Slovenia
6320

Study participating centre
Health Centre Nova Gorica
Rejčeva ulica 4
Nova Gorica
Slovenia
5000

Study participating centre
Health Centre Šentjur
Cesta Leona Dobrotinška 3b
Šentjur
Slovenia
3230

Study participating centre
Ambulanta za vse generacije d.o.o.
Potrčeva cesta 15
Ptuj
Slovenia
2250

Study participating centre
Zasebna pediatrična ambulanta dr. Zrilić
Potrčeva cesta 15
Ptuj
Slovenia
2250

Study participating centre
Pediatrija d.o.o
Kalohova ulica 18
Maribo
Slovenia
2000

Study participating centre
Pediatrinja d.o.o.
Hrenova ulica 6
Maribor

Slovenia
2000

Study participating centre
Health Centre Murska Sobota
Grajska ulica 24
Murska Sobota
Slovenia
9000

Sponsor information

Organisation
Probiotics International Ltd. (Protexin)

Sponsor details
Lopen Head
Somerset
Somerset
United Kingdom
TA13 5JH

Sponsor type
Industry

Website
http://www.protexin.com

ROR
https://ror.org/00dv58j78

Funder(s)

Funder type
Industry

Funder Name
Probiotics International Ltd. (Protexin)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the study contact.

IPD sharing plan summary
Available on request