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Enterosgel® in the treatment of atopic dermatitis in adults

Submission date
07/02/2017

Recruitment status
No longer recruiting

Registration date
08/02/2017

Overall study status
Stopped

Last Edited
09/11/2022

Condition category
Skin and Connective Tissue Diseases

[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
Skin conditions are the most common reason that people go to their General Practitioner (GP) with a new problem, with around 24% of the population a year consulting their GP with a skin problem. Atopic dermatitis (atopic eczema) is a condition that causes the skin to become itchy, red, dry and cracked. It is one of the most common skin conditions, affecting up to 20% of children and 3% of adults worldwide. Despite currently available effective treatments, there is a need for new treatments which could be safely used as frequent and/or long-term treatments. Intestinal (gut) bacteria may play a role in the development of atopic skin conditions, so treatments targeting the gut could provide a new approach for the prevention and management of these conditions. Intestinal adsorbents, medications which can help normalise the gut bacteria and remove toxins from the gut, are used to treat skin conditions in some countries including Russia and Ukraine. However, more research is needed to demonstrate that intestinal adsorbents can be beneficial in the treatment of skin conditions, at least in certain types of patients. The aim of this study is to assess the effectiveness of an over-the-counter intestinal adsorbent, Enterosgel®, in adult patients with acute dermatitis. The levels of selected substances in the blood (biomarkers) are also measured to investigate their role in dermatitis and to test whether they could be used to predict how patients respond to treatment.

Who can participate?
Patients aged 18 to 60 with acute dermatitis

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group receive Enterosgel® in addition to standard-of-care treatment. Participants in the other group receive only standard-of-care treatment. Each patient remains in the study for 28 days and attends two study visits at the medical practice (Days 0 and 14). In addition, a research nurse phones the patients on Days 3, 7, 21 and 28 to ask about symptoms, any adverse events (side effects) and treatment use. The first visit involves a thorough assessment of symptoms by a GP who does not know which group the patient is allocated to at the end of the visit. Patients are also asked to provide a blood sample to measures the levels of biomarkers, and to keep a daily diary about their symptoms and use of treatments until Day 28.

What are the possible benefits and risks of participating?
The researchers cannot promise participants any direct benefit, but participation in the study may provide important information to improve treatments for atopic skin conditions. The procedures performed in this study are used in routine care and do not pose any significant risks. Taking a blood sample can cause some minor discomfort. All medications are standard treatments for atopic dermatitis. Enterosgel® is not currently used for treating dermatitis in the UK, but is available to treat diarrhoea and food poisoning. No adverse reactions to this treatment have been reported. However, research suggests that nausea, vomiting or constipation can occur in very rare instances.

Where is the study run from?
1. The Village Practice (UK)
2. Pickering Medical Practice (UK)
3. Rame Group Practice (UK)
4. Rowen Surgery (UK)
5. Bradford Road Medical Centre (UK)
6. White Horse Health Centre, Westbury Group Practice (UK)

When is the study starting and how long is it expected to run for?
September 2016 to August 2023

Who is funding the study?
Bioline Products s.r.o

Who is the main contact?
1. Mrs Elena Markaryan
2. Dr Preeti Pandya

Contact information

Type(s)
Public

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Mrs Elena Markaryan

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ENT03UK

Study information

Scientific Title
Randomised, multi-centre study to assess efficacy, tolerability and safety of Enterosgel® in the treatment of acute atopic dermatitis in adults

Study objectives
The hypothesis is that the over-the-counter intestinal adsorbent, Enterosgel®, used in combination with standard-of-care treatment results in better clinical outcomes in the treatment of acute atopic dermatitis than standard-of-care treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 03/04/2017, ref: 17/NW/0131

Study design
4-week randomised controlled assessor-blinded multi-centre post-marketing efficacy and safety study of a medical device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Atopic dermatitis

Interventions
Patients will be randomised in 1:1 ratio using a computer-based randomisation tool (Sealed Envelope Ltd, UK) to:
1. Control group, who will receive standard of care treatment
2. Intervention group, who will receive standard of care treatment together with an intestinal adsorbent, over-the-counter medical device, Enterosgel® (Biotin Products s.r.o, Czech Republic) according to study-specific dosage, i.e. 2 tablespoons and 1 sachet a day for 14 days, and continuing on the same dosage on Days 14-28 if the GP determines on Day 14 that treatment should be continued.

Randomisation will be based on the minimisation method where treatment allocation will be stratified by study centre.

Each patient will remain in the study for 28 days and attend two study visits at the medical practice (Days 0 and 14). In addition, a research nurse will phone the patients on Days 3, 7, 21 and 28 to ask about symptoms, any adverse events and treatment use. The first visit will involve confirmation of eligibility, taking informed consent and a thorough assessment of symptoms by a GP who will be blinded from the treatment group the patient is randomised to at the end of the visit. Patients will also be asked to provide a blood sample for analyses of biomarkers, and to keep a daily diary about their symptoms and manifestations and use of treatments until Day 28.

Intervention Type
Device

Primary outcome measure
Dermatitis severity and symptoms, assessed by a blinded GP using the SCORing Atopic Dermatitis (SCORAD) Score on Day 14 (+/- 2 days)

Secondary outcome measures
1. Patient-reported dermatitis symptoms, measured with the Patient Oriented Eczema Measure (POEM) on Days 3, 7, 14, 21 and 28 (+/- 2 days for all)
2. Percentage of patients with improvement in the SCORAD score from Day 0 to Day 14 (+/- 2 days)
3. Percentage of patients with improvement in the POEM score from Day 0 to Days 3, 7, 14, 21 and 28 (+/- 2 days)
4. Patient-reported duration of individual dermatitis symptoms (n (%) days)*
5. Treatment success, defined as not requiring any treatment for dermatitis on Day 14 (+/- 2 days)
6. Duration of other concomitant symptoms (n (%) days)**
7. Duration of use of standard-of care treatment(s) (n (%) days)**

8. Tolerance and safety of Enterosgel®, assessed via adverse event (AE) reporting from first day of Enterosgel® intake until Day 28 (+/- 2 days)

* Symptoms are the same as the symptoms in the POEM questionnaire and will be recorded in a patient diary every day from Day 0 to Day 28 (+/- 2 days). Duration is reported as number of days the symptom lasted calculated based on the last and first day when the symptom was recorded in the questionnaire. Duration will also be reported as % of diary days the symptom was present.

** Other concomitant symptoms and treatment use will be recorded in a patient diary every day from Day 0 to Day 28 (+/- 2 days). Duration is reported as number of days the treatment was used calculated based on the last and first day when the treatment use was recorded in the questionnaire. Duration will also be reported as % of diary days the treatment was used

Exploratory outcomes:
1. Correlation between biomarkers (IgE, LPS, TNF-α) and dermatitis severity (SCORAD, POEM) on Day 0 and on Day 14
2. Change in IgE, LPS and TNF-α from Day 0 to Day 14

A +/- 2 day window is allowed for all phone calls/visits

Overall study start date
01/09/2016

Completion date
30/08/2023

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Has acute manifestations of dermatitis at the time of screening
2. Has a diagnosis of dermatitis evidenced by a read code (list of read codes provided in the protocol)
3. Aged 18 to 60
4. Able to give informed consent and complete the required study procedures, including providing a blood sample
5. Considered suitable to take part in the study in GP's opinion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44

Key exclusion criteria
1. History of intestinal atony (severe constipation due to bowel obstruction)
2. Fever (> 39 degrees Celsius)
3. Any other clinically significant skin condition in GP's opinion
4. A history of clinically significant allergic reactions in GP's opinion
5. Use of any clinical trial investigational medication or medical devices within the last 30 days before screening visit
6. Patients with known cancer of any localisation
7. Any underlying condition that could affect the patient’s participation in this study or the results of this study in GP's opinion
8. Pregnancy

Date of first enrolment
01/06/2022

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Village Practice
Thornton
United Kingdom
FY5 2TZ

Study participating centre
Pickering Medical Practice
Pickering
United Kingdom
YO18 8BL

Study participating centre

Rame Group Practice
Torpoint
United Kingdom
PL11 2PD

Study participating centre
Rowen Surgery
Chippenham
United Kingdom
SN15 2SB

Study participating centre
Bradford Road Medical Centre
Trowbridge
United Kingdom
BA14 9AR

Study participating centre
White Horse Health Centre, Westbury Group Practice
Westbury
United Kingdom
BA13 3FQ

Sponsor information

Organisation
Enteromed Ltd

Sponsor details
10 John Street
London
United Kingdom
WC1N 4EB

Sponsor type
Industry

ROR
https://ror.org/013bz8f47

Funder(s)

Funder type
Industry

Funder Name
Bioline Products s.r.o.

Results and Publications

Publication and dissemination plan
Study results will be submitted for presentation(s) at dermatology conference(s) and for publication in international peer-reviewed scientific journal(s).

Intention to publish date
30/11/2023

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No