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A randomized, blinded, clinical trial assessing the efficacy of superfine merino wool base layer garments (SMWBG) in children with Atopic Dermatitis (AD) measuring SCORAD, EASI, POEM and DSA scores

Submission date
08/01/2018

Recruitment status
No longer recruiting

Registration date
20/01/2018

Overall study status
Completed

Last Edited
14/01/2019

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Atopic dermatitis (AD) is an inflammatory skin disease affecting both children and adults. 'Atopic' means that the skin can react readily to environmental irritants and allergens. Over the past three decades the prevalence of atopic dermatitis has doubled or tripled in industrialised countries with some 15-20% of children and 2-10% of adults being affected. Its peak prevalence is highest in school-aged children and persists after puberty in up to 50% of children affected. Three main existing treatments, all with potential concerns, are traditionally prescribed in the treatment of AD including: topical corticosteroids (TCS), emollients and systemic treatments. TCS and emollients remain the mainstay of AD treatment. All the above treatments have side effects and researchers are yet to find a treatment that can be used long term without potential concerns. Therefore, the aim of this study is to assess whether merino wool has the ability to help prevent dermatitis from getting worse as a additional treatment option for patients with AD.

Who can participate?
Patients aged 6 to 25 with AD

What does the study involve?
Participants wear normal clothes for 5 weeks, wear Superfine Marino Wool Base Layer Garments (garments worn directly against the skin) for 5 weeks, then wear normal clothes for 5 weeks. Severity of AD is assessed during the three periods.

What are the possible benefits and risks of participating?
There may be no benefit in participating in this study, but these garments could improve the symptoms of AD. Discomfort may be minimized by a reduction in itchiness and redness, which should result in a decreased use and reliance on creams and ointments. There is however no

guarantee that this will happen. The information collected in this study will help researchers to learn more about the relationship between AD patients and their clothing, in particular merino wool. Female participants who become pregnant during the study need to inform the study staff and be taken off the study. There are no safety concerns associated with wearing wool garments whilst pregnant. This is done because pregnancy can in a small percentage of females change the inflammatory course of dermatitis in either a positive or a negative way, and this may affect the study outcome.

Where is the study run from?
Veracity Clinical Research (Australia)

When is the study starting and how long is it expected to run for?
June 2014 to July 2016

Who is funding the study?
Australian Wool Innovation (Australia)

Who is the main contact?
Dr Lynda Spelman

Contact information

Type(s)
Scientific

Contact name
Dr Lynda Spelman

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014-01-045-A-13

Study information

Scientific Title

A randomized, blinded, clinical trial assessing the efficacy of superfine merino wool base layer garments (SMWBG) in children with Atopic Dermatitis (AD) measuring SCORAD, EASI, POEM and DSA scores

Study objectives
Hypothesis (H)1: The fabric characteristics of Superfine Marino Wool Base Layer Garments (SMWBG) will be well tolerated by participants with AD.
H2: When SMWBG are worn by children and young adults they will experience a reduction in their AD symptoms and signs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by an independent HREC (Bellberry Ltd), 25/06/2014, ref: 2014-01-045-A-13

Study design
Blinded repeated measures self-controlled experimental design study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
A with-garment intervention phase (IP) where participants wore Superfine Marino Wool Base Layer Garments [SMWBG] for 5 weeks, was compared with pre-garment IP and post-garment IP where participant's normal clothing was worn.

This study assessed the tolerability and potential therapeutic effect of superfine merino wool base layer garments (SMWBG) (garments worn directly against the skin) in children and young adults with atopic dermatitis (AD). We assessed the severity of AD looking at SCORAD1, EASI2, POEM3 and DSA4.

Intervention Type
Other

Primary outcome measure
The tolerability of superfine Merino wool base layer garments measured using SCORing Atopic Dermatitis (SCORAD), (Eczema Area and Severity Index), Dermatitis Severity Assessment (DSA), and Patient Orientated Eczema Measure (POEM), during the Pre-Garment intervention Phase (5 week period with 3 visits scheduled including baseline scores), the With-Garment intervention Phase (5 week period with 2 visits scheduled), and the Post-Garment intervention Phase (5 week period with 2 visits scheduled)

Secondary outcome measures
Quality of life, measured using Dermatology Life Quality Index (DLQI), Childrens Dermatology Life Quality Index (CDLQI), Patient Orientated Eczema Measure (POEM), during the Pre-Garment intervention Phase (5 week period with 3 visits scheduled including baseline scores), the With-Garment intervention Phase (5 week period with 2 visits scheduled), and the Post-Garment intervention Phase (5 week period with 2 visits scheduled)

Overall study start date
25/06/2014

Completion date
19/07/2016

Eligibility

Key inclusion criteria
1. Participant and/or guardian have provided informed consent
2. Participant is of either sex and of any race/ethnicity and aged 6 to 25 years of age, at the time of screening
3. Participant has a diagnosis of dermatitis for at least six months, proven by itchy skin located, but not limited to skin creases (front of elbows, back of knees and around eyes and neck)
4. Participant's dermatitis severity should be stable with no recent hospitalisations, increased systemic steroid use or recurrent clinically significant cutaneous infections within the last 5 weeks prior to screening
5. Participant or guardian must be capable of completing written questionnaires
6. The participant must be capable of completing the procedural requirements of the protocol
7. Optional photographic collection for research purposes

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
25 Years

Sex

Both

Target number of participants
30

Key exclusion criteria
1. Participation in any clinical trials in the last 30 days prior to screening
2. Participant and or guardian(s) are unable to complete written questionnaires
3. Women of childbearing potential, who are pregnant or breastfeeding or intend to become pregnant (within 2 months of completing the trial)
4. Proven allergic contact dermatitis to merino wool by allergy patch testing
5. Males with a clothing size greater than 2XL as determined by Investigator and/or females with clothing size greater than 18
6. Participant is unable to wear garments for a minimum of 6 hours per day
7. Participant has any kind of disorder that, in the opinion of the Investigator may compromise the ability of the participant or guardian to give informed consent

Date of first enrolment
25/06/2014

Date of final enrolment
22/01/2016

Locations

Countries of recruitment
Australia

Study participating centre
Veracity Clinical Research
Australia
4102

Sponsor information

Organisation
Queensland Institute of Dermatology

Sponsor details
Entrance on Denman St
Greenslopes Private Hospital Campus
Greenslopes
Brisbane
Australia
4120

Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Australian Wool Innovation

Results and Publications

Publication and dissemination plan
Additional documents will be made available upon request. Please email trials@veracityclinicalresearch.com.au for access.

Clinical Research and Clinical Trials in Dublin. Titled: AWI002: Trials, Tribulations and the Value of Persisting with Non-Drug Related Clinical Trials – Superfine Merino Wool Base Layer Garments in Atopic Dermatitis
Dr Jesse Johnston presented an oral presentation at the Annual Scientific Meeting of the Australasian College of Dermatologists. A planned publication in a high-impact peer reviewed journal is in the process of being completed.

Intention to publish date
19/07/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/07/2018		Yes	No