ISRCTN91126037 https://doi.org/10.1186/ISRCTN91126037

Eczema and dry skin – observational analysis of patients prescription patterns and healthcare utilization

Submission date
27/06/2017

Recruitment status
No longer recruiting

Registration date
19/07/2017

Overall study status
Completed

Last Edited
31/10/2018

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
Emollients are moisturisers that are applied directly to the skin to reduce water loss and cover it with a protective film. They are the recommended first treatment for patients with dry skin and eczema in children under 12. A number of studies have shown emollients, in particular colloidal emollients, to be safe and effective for the treatment of dry skin and inflammatory skin conditions such as eczema. However, it is suspected that adherence with this recommendation is generally poor. This can be for a number of reasons, including emollients not being offered or prescribed, failure to prescribe adequate quantities and patients not using them as frequently as necessary for optimal benefit. There is limited evidence on the impact of the use of emollients in terms of cost avoidance and reduction in the use of topical corticosteroids (TCS). Topical corticosteroids are most commonly prescribed for eczema topically (applied directly to the skin). They have many functions but among other things they are very effective at temporarily controlling inflammation. Very strong or potent TCS should not be used for prolonged periods of time over large areas of eczematous skin, due to concerns about potential side effects. Whereas most TCS are not expensive, some TCS can be relatively costly. The aim of this study is to examine prescribing patterns in the UK and outcomes based on those prescriptions. In addition, the study looks at whether patients treated with emollients as their first treatment had similar or lower needs for TCS and/or antibiotics.

Who can participate?
Patients with dry skin and/or eczema

What does the study involve?
The patients' use of healthcare is analysed, including frequency of GP visits, prescriptions for dry skin and eczema, and the percentage of patients treated with TCS, antimicrobials and antibiotics. The costs to the NHS (cost of visits and medication) are also calculated.

What are the possible benefits and risks of participating?
The results of this study will be used to further assess the effectiveness and cost-effectiveness of emollients. This is a database analysis with no involvement from the patient's perspective so there are no risks or benefits of participating in the study.

Where is the study run from?
Johnson & Johnson Consumer Ltd (UK)

When is the study starting and how long is it expected to run for?
January 2007 to December 2014

Who is funding the study?
Johnson and Johnson

Who is the main contact?
Dr Gill Nelson

Contact information

Type(s)
Scientific

Contact name
Dr Gill Nelson

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16_198R

Study information

Scientific Title
Eczema and dry skin – observational analysis of patients prescription patterns and healthcare utilization: a retrospective observational cohort study

Study objectives

Prescribing emollients for patients with dry skin and/or eczema is associated with lower use of steroid-containing ointments and of antibiotics (versus non-prescribing of emollients as first line therapy), and lower overall cost of care. Differences in outcomes and costs between emollient brands or types exist.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Scientific Advisory Committee (ISAC) provided by Clinical Practice Research Datalink (CPRD), 12/01/2017, ref: 16_198R

Study design
Retrospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available as this is a database analysis

Health condition(s) or problem(s) studied
Dry skin and/or eczema

Interventions
All patients with dry skin and/or eczema in 2008 and 2012 will be identified. Of those, patients with at least 2 distinct emollient prescriptions within 6 months of index will be identified and included in the “Exposed” cohort. Patients with 2 healthcare exposures (visits or prescriptions) for dry skin and/or eczema in 6 months but no emollient prescriptions at any time will be included in the “Control” cohort. The observational period before the dry skin and/or eczema diagnosis will be assessed and only patients with continuous ≥ 12 months of medical history prior to diagnosis (“washout period”), and ≥ 24 months post dry skin and/or eczema diagnosis will be included. The index date will be the date of dry skin and/or eczema diagnosis in those patients with at least 12 months washout period (i.e., first diagnosis in at least 12 months – this constitutes the “clean” period).

The trialists analysed the costs to the NHS associated with skin-related prescriptions and utilisation of the primary care healthcare system over for 2 years following time of first diagnosis of dry skin and/or eczema. They investigated whether the act of prescribing emollients or a specific branded emollient would negatively impact the NHS budget. There was no follow-up period.

Outcomes were measured over 2 years, post-index date. Visits were estimated using the Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care 2015. Prescription costs were estimated using publicly-available cost per drug for 2015. The net ingredient cost (NIC) was obtained for all prescriptions and linked to all prescriptions within CPRD. The total cost per prescription was obtained by taking into consideration the amounts prescribed multiplied by the NIC per Quantity, as reported in the public documents. The perspective of this analysis is strictly that of the NHS – no other societal or otherwise related costs than the estimated cost for visits as per PSSRU and prescription costs using the NIC information were included in the total cost of care.

Intervention Type
Mixed

Primary outcome measure
Measured using CPRD database over a two year period from initial diagnosis (post-index):
1. Health care utilisation:
1.1 Frequency of GP visits
1.2. Prescriptions for dry skin and eczema

Secondary outcome measures
Measured using CPRD database over a two year period from initial diagnosis (post-index):
1. Percentage of patients treated with potent or very potent topical corticosteroids
2. Percentage of patients treated with antimicrobials and/or antibiotics

Overall study start date
01/01/2007

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Patients with dry skin and/or eczema in 2008 and 2012
2. Exposed cohort: patients with at least 2 distinct emollient prescriptions within 6 months of index
3. Control cohort: patients with 2 healthcare exposures (visits or prescriptions) for dry skin and /or eczema in 6 months but no emollient prescriptions at any time
4. Continuous ≥ 12 months of medical history prior to diagnosis (washout period) and ≥ 24 months post dry skin and/or eczema diagnosis. The index date will be the date of dry skin and/or eczema diagnosis in those patients with at least 12 months washout period (i.e., first diagnosis in at least 12 months – this constitutes the “clean” period)

Participant type(s)
Patient

Age group
All

Sex

Both

Target number of participants
1,570

Key exclusion criteria
1. Patients with concurrent skin diseases that are typically treated with topical corticosteroids (TCS) such as bullous pemphigoid, lupus, lichen planus, granuloma annulare, lichen sclerosis, alopecia areata and vitiligo
2. Patients with low-quality records or non-continuous data coverage
3. A diagnosis of dry skin-eczema during the washout period (12 months period prior to index diagnosis)

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Johnson & Johnson Consumer Ltd
United Kingdom
SL6 3UG

Sponsor information

Organisation
Johnson & Johnson Ltd

Sponsor details
Foundation Park
Roxborough Way
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Sponsor type
Industry

ROR
https://ror.org/03qwpn290

Funder(s)

Funder type
Industry

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The study will be conducted according to the International Committee of Medical Journal Editors (ICMJE) guidelines. For methodological issues, the STROBE checklist will be followed. This study is expected to inform cost-effectiveness analyses and will be published in a dermatology journal.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Rachel Weinstein (rweinst1@its.jnj.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2018		Yes	No