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Compliance with drug treatments and adjuvant barrier repair therapies are key factors for clinical improvement in mild to moderate acne

Submission date
08/06/2015

Recruitment status
No longer recruiting

Registration date
16/07/2015

Overall study status
Completed

Last Edited
14/09/2015

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
Acne is a common skin condition that causes spots to develop on the skin, most noticeably on the face, but also other areas such as the back and the chest. The condition can be mild and result in a few surface blackheads and whiteheads, or severe with deep, inflamed and pus-filled pustules and cysts. Treatment varies from special creams, lotions or gels (topical treatments available from pharmacies) to stronger creams and antibiotics (available only on prescription). Poor adherence to the treatment is a common reason for failure to treat acne successfully. This includes not getting the medication recommended, not using the medication, stopping taking the medication early or not understanding how to apply the medication. Here, we want to test in a real- life setting conditions impact of adherence to physician's instructions, recommendations and compliance to the treatments on clinical outcome in patients with mild to moderate acne.

Who can participate?
Adults that have mild to moderate acne needing to be treated with topical treatments with retinoid or antibiotics.

What does the study involve?
Participants are asked to comply with physician instruction and recommendations for treating acne. Prescribed treatments include specific anti acne drugs, facial cleansing products, and emollient and hydrating topical products. Each participant takes part in the study for 3 months.

What are the possible benefits and risks of participating?
Potential benefits include improvement of acne.

Where is the study run from?
University Hospital La Paz and Hospital Quirón Teknon (Spain)

When is the study starting and how long is it expected to run for?
October 2011 to November 2013

Who is funding the study?
Isdin SA, Barcelona (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ACTUO/01/2012

Study information

Scientific Title
Compliance with drug treatments and adjuvant barrier repair therapies are key factors for clinical improvement in mild to moderate acne: The ACTUO observational prospective multicenter cohort trial in 643 patients

Study objectives
To evaluate by means of an observational, epidemiological, non-interventional prospective 3-month, cohort trial carried out in 72 Dermatologic Services in Spain (ACTUO Trial) the adherence and compliance to antiacne treatments by means of a validated questionnaire (ECOB) to prescribed treatments on the clinical outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEIC (Centro Medico Teknon Hospital Quirón Teknon, del Grupo Hospitalario Quirón Barcelona Spain). October 2011, ref: ACTUO/ISDIN/01

Study design
Observational epidemiological non-interventional prospective 3-month, cohort trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mild to moderate acne

Interventions
The study was carried out in more than 600 subjects with mild-to-moderate acne with facial involvement. Prescribed treatments were:
1. Specific anti acne drugs: topical retinoids, topical antiseptics
2. Coadjuvant products: specific facial cleansing products, emollient and hydrating topical products
3. Total study duration per patient was 3 months

Intervention Type
Other

Primary outcome measure
Evaluation of the impact of adherence and compliance to the treatments on the clinical outcome in patients with mild to moderate acne.

Secondary outcome measures
Evaluation of the impact of the use of specific adjuvant treatments (facial cleansing, emollient moisturizing and lenitive specific topical products) on adherence level and entity of the clinical outcome obtained.

Acne severity was assessed at each visit with a 5-point score system (from 0 to 4), absolute count of lesions and percentage of patient reaching a ≥50% reduction in lesion numbers.

Adherence and Compliance were evaluated at visit 2 and visit 3 by means of validated 4-item questionnaire (ECOB) with a dichotomous classification: good adherence/compliance (ECOB score 4) and poor adherence/compliance (ECOB score <4). Poor compliance to treatment was defined as a different to expected answer on the ECOB questionnaire.a negative answer to question number 2 or number 3 of ECOB questionnaire.

Overall study start date
01/10/2011

Completion date
01/11/2013

Eligibility

Key inclusion criteria
Mild to moderate acne necessitating topical treatments with retinoid or antibiotics

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
Severe acne

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Spain

Study participating centre

University Hospital La Paz (Hospital Universitario La Paz)
Madrid
Spain
28046

Study participating centre
Hospital Quirón Teknon
Barcelona
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Sponsor information

Organisation
Isdin SA

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Sponsor type
Industry

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
Isdin SA, Barcelona (Spain)

Results and Publications

Publication and dissemination plan
Submitted to BMC Dermatology

Intention to publish date
30/07/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2015		Yes	No