ISRCTN75516184 https://doi.org/10.1186/ISRCTN75516184

Evaluation of the efficacy of treatment with ANW for facial acne

Submission date	Recruitment status	[_] Prospectively registered
06/07/2011	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2011	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2017	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acne is a common skin condition that causes spots, oily skin and sometimes skin that's hot or painful to touch, and often develops on the face. The aim of this study is to test the effectiveness and safety of ANW as a medical device for the treatment of facial acne.

Who can participate?
Patients aged over 18 with facial acne

What does the study involve?
Participants are randomly allocated to be treated with either the ANW solution or purified water (placebo/dummy drug). The treatments are sprayed on the face twice daily for 12 weeks. No other skin treatment for acne is allowed, except the ones agreed with the researcher at the start of the study.
Assessments are carried out after 2, 4, 8, 12 and 16 weeks for follow up of effectiveness and safety.

What are the possible benefits and risks of participating?
Results obtained with equivalent devices indicate that ANW may be effective in the treatment of acne. No side effects are expected from the use of this device.

Where is the study run from?
San Raffaele Scientific Institute (Italy)

When is study starting and how long is it expected to run for?
March 2011 to May 2012

Who is funding the study?
Applied Pharma Research (Switzerland)

Who is the main contact?
Prof. Santo Raffaele Mercuri

Contact information

Type(s)
Scientific

Contact name
Prof Santo Raffaele Mercuri

Contact details
Dermatology Unit
San Raffaele Scientific Institute and San Raffaele University Medical School Vita-Salute
via Olgettina, 60
Milano
Italy
20132

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the efficacy of treatment with ANW for facial acne

Acronym
ACNE_ANW

Study objectives
The hypothesis is that ANW works better than placebo in the treatment of facial acne (degree 2-3 of IGA scale)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Il Comitato Ethico Della Fondazione Centro San Raffaele del Monte Tabor Istituto Scientifio Ospedale San Raffaele - Milanom, 09/09/2010

Study design
Double-blind randomized monocentric placebo-controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the sponser details to request a patient information sheet

Health condition(s) or problem(s) studied
Facial acne

Interventions
1. ANW vs placebo
2. Two daily treatments (morning and evening for 12 consecutive weeks
3. Each daily treatment consists in spraying the product on the skin affected by acne (13 times of 100ul each to cover the entire face) and let it dry for at least 2 minutes, then in repeating the operation and let it dry again for at least 2 minutes

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The present pilot study will assess the efficacy and safety of ANW solution in the treatment of facial acne
2. Both the assessment of the IGA and the number of inflammatory (mainly papules and pustules) and non inflammatory (mainly comedones) lesions will serve as primary end-points for quantifying treatment efficacy, to be assessed at each planned visit, including the first (recruitment) visit
3. Non-inflammatory lesions (open -blackheads- or closed -white heads- comedones), are not expected to be affected by ANW treatment
4. Nevertheless, they will be counted in order to evaluate whether there is any effect on this parameter, either curative or comedogenic
5. The safety of the product will be monitored during the whole study by reporting all the Adverse Events in the CRF, diary

Secondary outcome measures
1. Subjects who will provide specific consent will be photographed by a standardized method, using high-resolution digital photography
2. In any case photos will be taken with a framing and/or post-acquisition elaboration preventing recognition of the photographed subject

3. A nine-score grading of acne severity will be performed by the Investigator according to his /her clinical judgement at each visit starting from scheduled visit 2
4. This assessment will considered modification of the clinical severity in comparison with the previous scheduled visit, in accordance to the following qualitative evaluation (as reported in proper CRF)
5. Each subject is invited to report daily in the diary his/her subjective evaluation regarding the treatment
6. Furthermore, a standardized questionnaire on Quality of Life assessment in subjects affected by facial acne (Acne-QoL) will be appended to the diary for self-administration at two visits, namely at study entry and after the 12-week treatment period (scheduled visit number 5)
7. The 19 questions of Acne-QoL are framed to be specific to site (... because of your facial acne) and time (... in the past week)
8. The measurement of psychosocial impact of disease has, until recently, been a relatively neglected component of the clinical paradigm
9. In acne, increasing recognition that objective clinical measures may be inadequate in assessing the overall impact and effect of this disease has led to the development of disease-specific psychometric instruments
10. The Acne-QoL questionnaire was developed specifically to assess health-related quality of life for clinical trials in acne and has been widely validated in several clinical studies

Overall study start date
08/03/2011

Completion date
31/05/2012

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Male or female patients with acne
2. Above age 18
3. Able to comply with the study procedures, in the opinion of the investigator, and able to give a voluntary written informed consent for participation in the trial
4. Diagnosis of severity of facial acne either 2 or 3 grade according to the Investigators Global Assessment (IGA) scale
5. The patient can exclude to become pregnant during the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
60

Key exclusion criteria
1. Pregnancy
2. Breastfeeding
3. More than one nodulo-cystic lesion per side of the face
4. Subject with facial acne who used any topical treatment in the last 7 days, and/or systemic antibiotic therapy in the last 30 days and/or systemic retinoid in the last six months
5. Cancer or history of cancer
6. Significant history of hematologic, cardiovascular, renal, neurologic, psychiatric, endocrinologic, metabolic, immunologic, or hepatic disease
7. Reported HIV infection
8. Known or suspected individual hypersensitivity to any component of the product
9. Use of hormonal contraceptives, stilbestrol/ d.e.s., primidone, fluoxetine, phenylpropanolamine, methylphenidate, troglitazone, gemfibrozil, cerivastatin, isotretinoin

Date of first enrolment
08/03/2011

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Italy

Study participating centre
San Raffaele Scientific Institute and San Raffaele University Medical School Vita-Salute
Milano
Italy
20132

Sponsor information

Organisation
Applied Pharma Research (Switzerland)

Sponsor details

via Corti 5
Balerna
Switzerland
CH-6828

Sponsor type
Industry

Website
http://www.apr.ch/site/index.html

ROR
https://ror.org/05c2q0q08

Funder(s)

Funder type
Industry

Funder Name
Applied Pharma Research (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration