The presence of Cutibacterium acnes on the skin of the shoulder after the use of benzoylperoxide

Published: 20-11-2018
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The objective is to evaluate if topical benzoyl peroxide reduces the presence of C. acnes on the skin of the shoulder compared to a topical placebo?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON48905

Source
ToetsingOnline

Brief title
PRE-PAIS Study

Condition

- Bacterial infectious disorders
- Bone and joint therapeutic procedures

Synonym
skin bacteria, Skin flora

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Anna fonds

Intervention

Keyword: Cutibacterium acnes/Propionibacterium Acnes, Infection, Prevention, Shoulder

Outcome measures

Primary outcome

Presence of C. acnes on the skin, by means of skin cultures.

Secondary outcome

Not applicable

Study description

Background summary

Cutibacterium acnes (formerly known as Propionibacterium Acnes) (C. Acnes) is one of the most frequent pathogens of infections after shoulder surgery. C. Acnes is a commensal, gram-positive anaerobic bacillus that resides in sebaceous glands associated with hair follicles and therefore the colonization is greater in the shoulder epidermis than other regions of the body. C. Acnes could be responsible for low-grade infections, after shoulder surgery, and it has been shown that it is the most commonly isolated bacteria after revision shoulder arthroplasty surgery. Standard surgical skin disinfection and preparation in combination with intravenous prophylactic antibiotics does not seem to be effective on reducing the bacterial load of C. acnes. Contamination of the surgical field with C. acnes occurs from (sub)dermal layer. If a relatively simple preoperative intervention, such as application of an ointment on the skin area that will be operated, can reduce the presence of C. acnes, this will probably lead to less postoperative infections. This will lead to an improvement of the well being of the patient and also a reduction of health-care costs.

Study objective

The objective is to evaluate if topical benzoyl peroxide reduces the presence of C. acnes on the skin of the shoulder compared to a topical placebo?

Study design

Double-blind randomised placebo-controlled trial.

Intervention

5 times application of an ointment (topical benzoylperoxide or placebo).

Study burden and risks

Investigating the effect of topical benzoyl peroxide on the incidence of C. Acnes makes it possible to optimize the treatment of future patients and therewith preventing postoperative infections. The risks are minimal in this study, and almost exclusively include possible side effects of the topical agents. The burden for participants contains 5 times application of an ointment and recording this on a data sheet. Furthermore, two times an appointment with the research employee of approximately 20 minutes.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574NA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Healthy volunteer who is willing to be participate during the course of 2 months
- 40 to 80 years old
- Living independently
- Instructable
- Able to apply ointment
- C. acnes present on the skin of the shoulder

Exclusion criteria

- Antibiotic use in the past 2 months
- Previous surgery on one or both shoulders
- Corticosteroids infiltration in the shoulder that will be investigated in the past 3 months
- Allergy for benzoil peroxide
- Already using a benzoil peroxide ointment
- Usage of tretinoin or adapalene
- Pregnant
- Breastfeeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Benzoylperoxide TEVA hydrogel
Generic name:	Benzoylperoxide hydrogel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19955
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-004817-19-NL
CCMO	NL63995.091.17
OMON	NL-OMON19955

Study results

Date completed:	31-05-2019
Actual enrolment:	30