Multicenter, national non-interventional study including a registry and a prospective cohort of patients with common scab. (Epigale)

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Study | Finalised

Administrative details

EU PAS number

EUPAS43279

Study ID

43280

DARWIN EU® study

No

Study countries

France

Study description

Main objective: to evaluate the% of patients cured on day 28 (±7 days) in patients with common scab and treated with Ascabiol® in real life conditions. Secondary objectives: to describe • Epidemiological and clinical characteristics of treated patients • Respect of the prescription methods (dosage and good use) of the 10% benzyl benzoate emulsion • treatment of the family • treatment of the environment • Predicting factors of treatment success at D28 7 days (S4) • Recurrence rate at J84 (S12) and predictors of recurrence. • Registry data

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 19 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eric Caumes

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/09/2018

Study start date
Planned: 01/11/2018

Actual: 28/01/2019

Date of final study report
Planned: 01/01/2020

Actual: 02/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zambon France

Study protocol

STUDY PROTOCOL.pdf (122.15 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate the% of patients cured on day 28 (±7 days) in patients with common scab and treated with Ascabiol® in real life conditions.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Ascabiol

Medical condition to be studied

Acarodermatitis

Population studied

Short description of the study population

Patients with common scab and treated with Ascabiol® in real life conditions

Criteria for participation in the registry: all patients

- more than 1 month old
- outpatient
- visiting for untreated common scab
- giving their oral consent to participation (over 18 years) or for which the parents give their participation agreement (under 18 years).

Criteria for participation in the cohort: all patients

- included in the registry
- treated with Ascabiol® monotherapy

Criteria for non-participation in the registry and monitoring:

- known pregnancy
- breastfeeding

- hyperkeratotic scabies

- scabies already treated in the last 6 month

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Scabies

Estimated number of subjects

300

Study design details

Data analysis plan

The analysis of the primary endpoint will be conducted on all patients included in the cohort and reviewed at D28 (±7 days). The 95% confidence interval will be calculated. Sensitivity analyzes will be conducted. Secondary end points: the analyzes of the secondary end points will be descriptive. The search for predictors of treatment failure on day 28 (W4) and recurrence on day 84 (W12)

will be done by univariate analyzes to select the factors to be considered in a multivariate logistic regression model.

Documents

Study results

EPIGALE Rapport VF 2021 Mars 08 + Signatures.pdf (632.55 KB)

Study publications

Caumes E, Marty M, Cadot M, Boulanger P, Rousseaux C, Petit A. A prospective co…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No