# A Double-Blind, Vehicle-Controlled, Randomized Withdrawal and Treatment Extension Study to Assess the Long-Term Efficacy and Safety of Ruxolitinib Cream in Participants With Vitiligo

Published: 28-12-2020
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Primary Objective:To evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Skin and subcutaneous tissue disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51116

**Source**
ToetsingOnline

**Brief title**
TRuE-V LTE Study

### Condition

- Skin and subcutaneous tissue disorders NEC

**Synonym**
leucoderma, white patches of skin

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Incyte Corporation
**Source(s) of monetary or material Support:** Incyte Corporation

## Intervention

**Keyword:** Ruxolitinib, Vehicle-Controlled, Vitiligo

## Outcome measures

### Primary outcome

For participants who are randomized in Cohort A: * Time to relapse (defined as

< F-VASI75)

### Secondary outcome

For participants who are randomized in Cohort A: * Time to maintain * F-VASI90

response

and:

* Proportion of participants who achieve F-VASI50/75/90 during the extension

treatment period.

* Actual measurements, change, and percentage change from baseline in F-VASI.

* Proportion of participants who achieve T-VASI50/75/90 during the extension

treatment period.

* Actual measurements, change, and percentage change from baseline in T-VASI.

* Actual measurements, change, and percentage change from baseline in F-BSA.

* Actual measurements, change, and percentage change from baseline in T-BSA.

* Proportion of participants achieving a VNS of *4 * A lot less noticeable* or

*5 * No longer noticeable* during the extension treatment period

# Study description

### Background summary

Ruxolitinib cream is a topical formulation of ruxolitinib phosphate under development for the treatment of participants with AD, AA,plaque psoriasis, and vitiligo. Ruxolitinib phosphate is an inhibitor of the JAK family of protein TYKs. Inflammatory cytokines are strongly implicated in the pathogenesis of several dermatologic diseases. Because JAKs serve to translate extracellular signals from a number of relevant cytokines and growth factors upregulated in inflammatory diseases such as AD, AA, plaque psoriasis,and vitiligo, JAK inhibitors represent potential therapeutic agents for these disease states.

This is a Phase 3, double-blind, vehicle-controlled, randomized withdrawal and treatment extension study that will enroll eligible participants who have completed either Study INCB 18424-307, conducted at the AMC (NL70922.018.20)

### Study objective

Primary Objective:
To evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo.

### Study design

Key Secondary Objective:
To evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo

Other Secondary Objective:
To further evaluate the efficacy of ruxolitinib cream

### Intervention

ruxolitinib cream 1.5% /:vehicle

### Study burden and risks

Burden and risks: - Possible side effects from the treatment (side effects are described in Appendix D of the ICF) - Discomfort, soreness, bruising: in rare cases infection, light headedness/fainting from blood drawing - Rash or irritation from ECG sticky pads. - Commitment to follow instructions associated with the study treatment and visits schedule

Currently, there are no approved therapies for vitiligo, and treatments are

empirical and directed by the available clinical guidelines. Current therapies often do not lead to satisfactory response, and there are limitations and safety concerns with long-term use of some therapies, including topical or oral corticosteroids and calcineurin inhibitors. Given the psychosocial burden and stigma that has been reported in this disease, patients with vitiligo warrant access to new studies.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

1. Currently enrolled and receiving treatment in INCB 18424-306 or INCB 18424-307 studies evaluating ruxolitinib cream in participants with vitiligo.

2. Currently tolerating ruxolitinib cream in the parent study and no safety concerns per investigators judgment.
3. Has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements

### Exclusion criteria

1. Has been permanently discontinued from study treatment in the parent study for any reason.
2. Participants with an uncontrolled intercurrent illness or any concurrent condition that, in the investigator's opinion, would jeopardize the safety of the participant or compliance with the Protocol. 3. Pregnant or breastfeeding woman

## Study design

### Design

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|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 06-09-2021 |
| Enrollment: | 10 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | RUXOLITINIB CREAM |

| | |
|---|---|
| Generic name: | INCB018424 PHOSPHATE CREAM |

## Ethics review

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| Approved WMO Date: | 28-12-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 29-03-2021 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 10-11-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 14-03-2022 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2020-000987-53-NL |

| Register | ID |
| --- | --- |
| CCMO | NL75444.018.20 |