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TAR-0520 gel in EGFR inhibitor-induced folliculitis

Submission date	Recruitment status	[X] Prospectively registered
22/07/2024	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/01/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/01/2025	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cetuximab and panitumumab have become the standard treatment for patients with metastatic colorectal cancer without RAS gene mutation. However, these EGFR inhibitors induce a broad spectrum of cutaneous toxicities (skin side effects) in 75-90% of patients including the folliculitis rash involving the face, upper torso and scalp. The folliculitis rash appears within 1-2 weeks of anti-EGFR therapy and peaks around 3-5 weeks of treatment. There is no approved treatment to prevent or treat EGFR-induced folliculitis.
Tarian Pharma has developed a new topical gel for the prevention and treatment of EGFRi-induced folliculitis. This study aims to confirm the good safety of TAR-0520 gel in colorectal cancer patients treated with cetuximab or panitumumab; and explore, in the same patients, the effects of TAR-0520 gel on the extent and severity of EGFRi-induced folliculitis.

Who can participate?
Patients aged 18 years and over with metastatic colorectal carcinoma planned to be treated with cetuximab or panitumumab injections as part of their chemotherapy

What does the study involve?
Participants are randomly allocated to receive either the topical active TAR-0520 gel or its vehicle (the same formulation without the active drug). The study will include a 7-day treatment period with once daily applications of the test product followed by a treatment-free period until the start of the next chemotherapy cycle (usually 7 days later). The study duration will cover four complete chemotherapy cycles, thus lasting at least 56 days and including four periods of 7 days of test product applications followed by a treatment-free period.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Tarian Pharma (France)

When is the study starting and how long is it expected to run for?
July 2024 to September 2026

Who is funding the study?
Tarian Pharma (France)

Who is the main contact?
Dr Janusz Czernielewski, janusz.czernielewski@tarianpharma.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2024-516339-28-00

Protocol serial number
TARIAN 007

Study information

Scientific Title
A Phase II multicentric, randomised, double-blind, placebo-controlled study of TAR-0520 gel in EGFR inhibitor-induced folliculitis

Study objectives
TAR-0520 gel will show good local safety and will reduce EGFR inhibitor (EGFRI)-induced folliculitis severity in colorectal cancer patients treated with anti-EGFR monoclonal antibodies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/11/2024, Ethics Committee Sud Mediteranee 1 (Institute Paoli Calmette, 232 Boulevard de Sainte Marguerite , Marseille, 13009 , France; +33 (0)491744256; cppsudmed1@gmail.com), ref: TARIAN 007

Study design
Phase II multicentric double-blind randomized placebo-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Prevention, Safety

Health condition(s) or problem(s) studied
Prevention of EGFRI-induced folliculitis in colorectal cancer patients treated with ant-EGFR antibodies

Interventions
A Phase II, multicentric, randomized, double-blind, placebo-controlled, parallel-group study to confirm the good safety profile and to explore the preventative effect of topically applied TAR-0520 gel on folliculitis developed in metastatic colorectal cancer (mCRC) patients treated with monoclonal anti-EGFR antibodies.

Approximately 60 mCRC patients will be included in this study and receive either the topical active TAR-0520 gel or its vehicle (same formulation without the active) in a 1:1 ratio. A stratification will ensure that the same proportion of patients treated with cetuximab or panitumumab will be found in the two arms.

The treatment schematic will thus include a 7-day treatment period with once-daily applications of the test product followed by a treatment-free period until the initiation of the next chemotherapy cycle (usually 7 days later). The study duration will cover four complete chemotherapy cycles, thus lasting at least 56 days and including four periods of 7 days of test product applications followed by a treatment-free period.

The expected duration of the study, from the inclusion of the first subject to the discharge of the last subject, is approximately 21 months.
The end date of the clinical trial is defined as the discharge date of the last subject.
The expected duration of recruitment (i.e. from the first to the last subject inclusive) is approximately 18 months.
Including the selection phase (up to 6 weeks), the maximum duration of participation in the study for a subject will be 14 weeks.

Intervention Type

Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
TAR-0520

Primary outcome(s)
The safety profile of TAR-0520 gel: the safety assessment will be conducted for all subjects at the screening visit (from the date of ICF signature) and at every subsequent visit. Any change in this assessment will trigger an AE report. The safety conclusions will thus be based on the comparative analysis of the AEs reported in the two treatment arms.

Key secondary outcome(s))
The preventive effectiveness of TAR-0520 gel will be measured using the modified Common Terminology Criteria for Adverse Events (CTCAE) scale, a Facial folliculitis severity score, and a patient assessment of severity (modified Functional Assessment of Cancer Therapy-EGFRI 18 [FACT-EGFRI 18]). The measurements will be performed at the baseline visit (D1-Visit 2) and then at D1 - Visits 3, 4, 5 and 6, just before the EGFRI-antibody intravenous infusion.

Completion date
15/09/2026

Eligibility

Key inclusion criteria
1. Male or female, who is at least 18 years of age or older at the screening visit
2. Clinical diagnosis of metastatic colorectal carcinoma planned to be treated with cetuximab or panitumumab injections as part of the chemotherapy protocol
3. Patients who can understand and sign the Informed Consent Form, can communicate with the investigator, can understand and comply with the requirements of the protocol, and can apply the study gel by himself/herself or have a giver who can apply the products
4. Predicted life expectancy ≥3 months
5. Willing and able to comply with all of the time commitments and procedural requirements of the clinical trial protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

75 years

Sex
All

Key exclusion criteria
1. Patient with a medical history of EGFRi treatment in the past 2 years
2. Patient has any underlying physical or psychological medical condition that, in the opinion of the Investigator, would make it unlikely that the patient would comply with the protocol or complete the study per protocol.
3. Any uncontrolled or serious disease, or any medical or surgical condition, that may put the subject at significant risk (according to the Investigator's judgment) if he/she participates in the clinical trial.
4. Patient has a history of other skin disorders (eg, atopic dermatitis, psoriasis, recurrent skin infections), or a history of illness that, in the opinion of the Investigator, would confound the results of the study
5. Significant skin disease other than EGFRI-induced acneiform lesions within the same body areas planned for study drug application
6. Has a beard that would interfere with administration of study drug and assessment of study endpoints
7. Active infection within the treatment area or in other body areas that requires initiation of systemic antibiotics
8. Known or suspected allergies or sensitivities to any components of any of the study drugs (see Investigator's Brochure/Product label)
9. Female who is pregnant or lactating
10. Female who intends to conceive a child during the clinical trial

Date of first enrolment
20/01/2025

Date of final enrolment
15/06/2026

Locations

Countries of recruitment
France

Study participating centre
Institut Paoli Calmettes
232 Bld Ste Margueritte
Marseille
France
13273

Sponsor information

Organisation
Tarian Pharma

Funder(s)

Funder type
Industry

Funder Name
Tarian Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date