Safety of topical 5-FU cream in patients carrying a clinically relevant DPYD variant – The DPYDIX study

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To prospectively study if patients carrying clinically relevant DPYD variants (DPYD*2A, c.2846A>T, c.1236G>A/HapB3, c.1679T>G) are more at risk for developing moderate/severe vesicles or bullae with 5-FU cream.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON20542

Source
Nationaal Trial Register

Brief title
DPYDIX

Condition

- Skin neoplasms malignant and unspecified

Health condition

Actinic keratosis, morbus Bowen or superficial basal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting de Merel

Source(s) of monetary or material Support: Stichting de Merel

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Appearing of moderate or severe vesicles or bullae in patients treated with 5-FU cream

Secondary outcome

- Pharmacokinetics of 5-FU cream. - Appearing of erythema, swelling, erosion, crusting, scaling, itching, diarrhea and/or fatigue. - Severity of pain and burning sensation. - Time to onset of severe 5-FU cream related toxicities; appearing of vesicles/bullae, erythema, swelling, erosion, crusting, scaling, itching, diarrhea and/or fatigue. - Tumour response at 3 months.

Study description

Background summary

Rationale: Recently it was shown that DPYD genotype-based dose reductions improved patient safety of fluoropyrimidine treatment. A limitation of previous research is that the additional value of DPYD genotype-based dosing is based on therapy with 5-fluoropyrimidine (5-FU; intravenous) and capecitabine (oral), while there is a third application of 5-FU; topical 5-FU (Efudix 5% cream). Objective: To study if patients who carry clinically relevant DPYD variants (DPYD*2A, c.2846A>T, c.1236G>A/HapB3, c.1679T>G) are at a higher risk for developing severe 5-FU cream-related toxicity. Study design: Prospective, observational clinical trial. Of patients receiving 5-FU cream, one blood sample will be withdrawn before or during therapy for DPYD genotyping. On five time points (1, 2 and 3 weeks after start therapy, with stop therapy and 3 months after start) adverse events will be evaluated using visual inspection of the treated area and patients will be asked to complete diaries to obtain information about adverse events. Study population: Adult patients planned to receive 5-FU cream are asked to participate in the study. Main study parameters/endpoints: Severe toxicity in patients treated with 5-FU cream. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risk of blood withdrawals is negligible.

Study objective

To prospectively study if patients carrying clinically relevant DPYD variants (DPYD*2A, c.2846A>T, c.1236G>A/HapB3, c.1679T>G) are more at risk for developing moderate/severe vesicles or bullae with 5-FU cream.

Study design

First patient inclusion planned in November 2019.

Intervention

-

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - Age ≥ 18 years - Able to understand the written information and able to give informed consent - Planned treatment with topical 5-FU cream (Efudix) for any indication - Possibility to take photos of the treatment area at the designated times and send them digitally

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - Prior treatment with fluoropyrimidines - Known allergy to (components of) 5-FU cream - Pregnancy, breast-feeding, active child wish - Concomitant use of systemic retinoids - Patients with known substance abuse, psychotic disorders, and/or other diseases expected to interfere with study or the patient’s safety in the opinion of the treating physician

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2019
Enrollment:	550
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	09-10-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 54797
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8075
CCMO	NL70969.078.19
OMON	NL-OMON54797

Study results