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Efficacy and safety of topical tocopherols in oral biopsies

Submission date	Recruitment status	[ ] Prospectively registered
19/04/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/09/2024	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the effectiveness of tocopherol acetate oral gel in reducing pain in patients undergoing oral biopsy (tissue sample). VEA filme os is a medical device in an oily gel formulation based on tocopherol acetate (vitamin E) used for the prevention and treatment of oral mucositis. Vitamin E promotes the healing of the skin and mucous membranes. Vea filme os forms a protective film and isolates the lesion in the mouth, and has already been used for some time to reduce surgical wound discomfort in patients undergoing oral biopsy.

Who can participate?
Adult patients who are undergoing an oral biopsy

What does the study involve?
One group receives standard of care (i.e. chlorhexidine) while the second group receives topical tocopherol gel treatment. Participants in the second group undergo three topical applications a day for 7 days after the oral biopsy, which involves spreading the gel on the lesion until it is covered. It is not necessary to massage and it is advisable to avoid touching the area even with the tongue for at least 1-2 minutes to favour the formation of the protective film. Patients are contacted by telephone as usual. Pain is assessed on days 1 and 6. Intake of painkillers will be recorded and evaluated.

What are the possible benefits and risks of participating?
There are no known undesirable effects related to the use of tocopherol acetate oral gel. Vitamin E toxicity is rare, but in high doses it can cause bleeding risk, as well as muscle weakness, fatigue, nausea and diarrhoea. Since the gel is applied to the mouth, sticks to the tissue and is ingested by the patient in minimal amounts, there is no risk of systemic overdose.

Where is the study run from?
HULKA srl (Italy)

When is the study starting and how long is it expected to run for?
January 2022 to July 2024

Who is funding the study?
HULKA srl (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CESC 330n/AO/23

Study information

Scientific Title
Comparative efficacy of tocopherol (VEA film os) versus chlorhexidine in patients undergoing oral biopsies: a randomized case-control study

Acronym
FOS

Study objectives
Evaluated topical application of a tocopherol-based gel can affect postoperative discomfort in oral biopsies

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 02/02/2023, Comitato Etico per La Sperimentazione Clinica Della Provincia Di Padova (Azienda Ospedale Università via Giustiniani 1, 35128, Padova, Italy; +39 (0)498215107; prc.unitaricercaclinica@aopd.veneto.it), ref: CESC 330n/AO/23

Primary study design
Observational

Study design
Observational case-control study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oral lesions

Interventions
Current interventions as of 10/09/2024:

Patients with oral lesions requiring biopsy will be recruited. One group (control) receive standard of care i.e. chlorhexidine while the second group (case) receive topical tocopherol gel treatment. On days 1 and 6, the discomfort following the biopsy will be assessed using a visual analog scale (VAS).

The study primary variable is the pain-related visual analogue scale (VAS-D) on the first and sixth postoperative day in patients who applied topical Vea filme os three times a day for 7 days on single or multiple oral mucosal biopsy samples. Concomitant intake of painkillers is recorded and evaluated. The same data is collected for control group.

The statistical analysis is done with a Student's t-test and carried out with R 4.1 (R Foundation for Statistical Computing, Vienna, Austria). A p-value of less than 0.05 is considered statistically significant. The postoperative discomfort assessment is conducted by telephone on the sixth day.

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Previous interventions:

Patients with oral lesions requiring biopsy will be recruited. One group (control) receive standard of care i.e. no treatment while the second group (case) receive topical tocopherol gel treatment. On days 1 and 6, the discomfort following the biopsy will be assessed using a visual analog scale (VAS).

The study primary variable is the pain-related visual analogue scale (VAS-D) on the first and sixth postoperative day in patients who applied topical Vea filme os three times a day for 7 days on single or multiple oral mucosal biopsy samples. Concomitant intake of painkillers is recorded and evaluated.

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significant. The postoperative discomfort assessment is conducted by telephone on the sixth day.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Tocopherol acetate oral gel with applicator

Primary outcome(s)
Discomfort measured using a pain-related visual analog scale (VAS) on days 1 and 6

Key secondary outcome(s)
Complications recorded by interviewing the patient after 1 and 6 days

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Patients undergoing biopsy of the oral cavity at the UOC Dental Clinic
2. Patients able to read and understand the information sheet and give informed consent
3. Patients who, after having been informed in detail about how to use Vea Filme os, have complied with the intake schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Current inclusion criteria as of 10/09/2024:

1. Patients with contraindications to surgery
2. Patients unable to give consent
3. Minor patients
4. Patients receiving antiangiogenic therapy
5. Patients receiving immunomodulator therapy
6. Patients with hypersensitivity to the Vea Filme os device

Previous exclusion criteria:

1. Patients with contraindications to surgery
2. Patients unable to give consent
3. Patients who took painkillers during the six study days
4. Minor patients
5. Patients receiving antiangiogenic therapy
6. Patients receiving immunomodulator therapy
7. Patients with hypersensitivity to the Vea Filme os device

Date of first enrolment
28/02/2023

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Italy

Study participating centre
University of Padova
Clinical Dentistry
Department of Neurosciences
Padova
Italy
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Sponsor information

Organisation
HULKA srl

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Patients accept the use of data for the purposes of scientific publication. Absolute anonymity in data processing is guaranteed.

IPD sharing plan summary
Stored in non-publicly available repository