

# Use of Oraqix® in individuals with desquamative gingivitis undergoing non-surgical periodontal treatment

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|----------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>19/03/2026   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>27/08/2026 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>27/08/2026       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The intervention involves the application of Oraqix®, a lidocaine-prilocaine thermosetting gel, to provide localized anesthesia in patients with desquamative gingivitis, peeling or inflamed gum tissue caused by certain diagnosed immunerelated mouth conditions, undergoing non-surgical periodontal therapy. This approach aims to combine effective periodontal therapy with minimized procedural pain, improving both patient tolerance and clinical outcomes in individuals with fragile gingival tissue due to desquamative gingivitis.

### Who can participate?

Adult patients who had been diagnosed with desquwith amative gingivitis and still had at least four teeth on each side of their upper or lower jaw.

### What does the study involve?

Before the procedure, the clinician will assess the extent of gingival involvement and carefully remove any surface plaque to ensure optimal gel contact. Oraqix® will then be applied subgingivally into the periodontal pockets using a specialized dispensing tip, allowing the anesthetic to penetrate the gingival sulcus and provide targeted pain relief. The gel sets at body temperature, forming a thin, localized layer that numbs the tissue without the need for injections, thus minimizing discomfort and post-treatment numbness. After a brief waiting period to allow the anesthetic effect to develop, patients will undergo scaling and root planing, during which the clinician will remove plaque and calculus from the tooth surfaces and beneath the gum line. The procedure may be repeated in multiple quadrants depending on the patient's needs, with additional Oraqix® applied as necessary to maintain comfort.

Throughout the treatment, clinicians will monitor patients for pain, sensitivity, or any adverse reactions, and patients will be asked to report their comfort levels using a standardized pain scale. Following completion of the therapy, the clinician will gently rinse the treated areas and provide post-procedure care instructions, emphasizing careful oral hygiene and monitoring for any local irritation or discomfort.

What are the possible benefits and risks of participating?

Participation in this study may provide benefits such as reduced pain during periodontal treatment through the use of a non-injectable anesthetic gel (Oraqix®), improved comfort during procedures, and potentially better tolerance of oral hygiene and therapy. Participants will also contribute to research aimed at improving pain management in patients with desquamative gingivitis.

Possible risks include mild local reactions such as temporary irritation, redness, or a burning sensation at the application site. There is also a possibility of incomplete anesthesia, which may result in some discomfort during treatment. Rarely, allergic reactions or systemic effects such as dizziness or palpitations may occur.

Where is the study run from?

University of Turin, Italy.

When is the study starting and how long is it expected to run for?

January 2023 to November 2025.

Who is funding the study?

University of Turin, Italy.

Who is the main contact?

Prof Paolo Giacomo Arduino, [paolo.arduino@gmail.com](mailto:paolo.arduino@gmail.com)

## Contact information

### Type(s)

Principal investigator, Public, Scientific

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

Efficacy of a non-injection thermosetting anesthetic gel in non-surgical periodontal therapy for patients with desquamative gingivitis: a randomized controlled split-mouth study

**Acronym**  
OrGDNST

## **Study objectives**

**Ethics approval required**  
Ethics approval required

**Ethics approval(s)**  
Approved 08/10/2022, Institutional Ethics Committee of the "AOU Città della Salute e della Scienza" / CIR DENTAL SCHOOL (Via Nizza 230, Turin, 10126, Italy; +39 011 6331522; segr\_cirdental@unito.i), ref: 0058273

**Primary study design**  
Interventional

**Allocation**  
Randomized controlled trial

**Masking**  
Blinded (masking used)

**Control**  
Placebo

**Assignment**  
Single

**Purpose**  
Treatment

## **Study type(s)**

**Health condition(s) or problem(s) studied**  
Autoimmune desquamative gingivitis.

**Interventions**  
The study was a split-mouth, examinerblinded, randomized, and controlled study. Randomization was performed using a computer-generated randomization sequence. Allocation was concealed using sealed, opaque envelopes that were opened at the time of treatment to assign the intervention to each side of the mouth in this split-mouth study design.

All procedures were carried out by a qualified dental hygienist in a single sitting (PC). The questionnaire administration and data entry were conducted by another researcher (MC). The intrapocket anaesthesia gel (Oraqix®; Dentsply International, York, PA, USA) was applied prior to NSPT. Oraqix® contains lidocaine and prilocaine (25 mg g-1 each) in a thermosetting agent. The anaesthesia gel is fluid at room temperature and increases its viscosity after application in the gingival sulcus.  
Each patient served as their own control: one side (test) received Oraqix®, while the

contralateral side (control) received placebo. The test agent was applied using a blunt-tipped applicator in a 1.7 ml cartridge ( $\approx 42.5$  mg of each anaesthetic); the placebo consisted of liquid paraffin, used in equivalent volume and mode of application. After applying a latex-free cheek and lip retractor (OptraGate®), Oraqix® or a placebo was applied on the designated sides. The gel was left in situ for 30 seconds before starting instrumentation. Periodontal debridement was performed using a piezoelectric ultrasonic scaler (EMS Piezon®) with a standard insert.

## **Intervention Type**

Device

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Oraqix®

## **Primary outcome(s)**

1. Pain perception measured using Visual Analogue Scale (VAS) with a numeric scale (0=no pain, 100=worst pain ever reported), and by the Verbal Rating Scale (VRS) (0=no pain, 1=mild pain, 2=moderate pain, 3=severe pain, 4=unbearable) at Immediately and after 3 days of surgery

## **Key secondary outcome(s)**

## **Completion date**

03/11/2025

# **Eligibility**

## **Key inclusion criteria**

Patients included were of both sexes, aged over 18 years, with the following characteristics:

1. Presence of desquamative gingivitis, associated with Oral Lichen Planus, Mucous Membrane Pemphigoid, or Pemphigus Vulgaris
2. Confirmed histopathologic and immunofluorescence diagnosis
3. At least four teeth per hemiarch

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

18 Years

## **Upper age limit**

80 Years

## **Sex**

All

**Total final enrolment**

40

**Key exclusion criteria**

1. Pregnancy or breastfeeding
2. Known hypersensitivity to amide anaesthetics
3. Epithelial dysplasia
4. Edentulism
5. Inability to attend follow-up visits

**Date of first enrolment**

16/01/2023

**Date of final enrolment**

26/09/2025

**Locations****Countries of recruitment**

Italy

**Sponsor information****Organisation**

University of Turin

**ROR**

<https://ror.org/048tbm396>

**Funder(s)****Funder type****Funder Name**

Università degli Studi di Torino

**Alternative Name(s)**

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Italy

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available