

# Assessing efficacy of a TLC-NOSF dressing on DFUs: The Explorer study

The announcement by Urgo Medical of the pioneering Explorer study into the efficacy of UrgoStart® Contact for treating diabetic foot ulcers (DFUs) is an exciting development in the management of these potentially devastating wounds. Some 2–10% of people with diabetes develop DFUs (International Diabetes Federation, 2012), but despite the high associated mortality there is a dearth of high-quality research to guide treatment (Dumville et al, 2012; Game et al, 2012).

The Explorer study is a double-blind randomised controlled trial (RCT), the gold standard for clinical research. Conducted across five European countries, with a large sample size and a long treatment period and follow-up, this ambitious trial aims to objectively assess UrgoStart® Contact, a technology lipidocolloid (TLC) dressing with nano-oligosaccharide factor (NOSF).

## BACKGROUND

UrgoStart® Contact consists of carboxymethylcellulose particles spread in a petroleum jelly network and impregnated with NOSF over a non-woven, non-occlusive, soft-adherent polyester layer. On contact with exudate, hydrocolloid particles form a gel that interacts with the petroleum jelly to make a lipidocolloid film, creating a moist environment within the wound. This attribute has been proven to promote healing (Bernard et al, 2005) and prevent adhesion (Urgo, data on file, 2010).

The TLC enables NOSF to cover the entire wound and to neutralise the activity of matrix metalloproteases (MMPs; Lobmann et al, 2002; 2006; Liu et al, 2009). MMPs occur in unusually high concentrations in DFUs and, in ischaemic conditions, are associated with poor wound healing (Yager and Nwomeh, 1999; Liu et al, 2009). Clinically, it has demonstrated improved healing in patients with DFUs (Richard et al, 2012) and with venous leg ulcers (Schmutz et al, 2008; Meaume et al, 2012). While several other products reduce the activity of MMPs in the wound bed, results from RCTs have been inconclusive (Veves et al, 2002; Vin et al, 2002).

## THE EXPLORER STUDY

The study commenced in January 2013 and will finish in December 2015. It will run in 68 centres across France, Germany, Italy, Spain, and the UK. The required number of participants for inclusion is 238.

## Study population

Participants, recruited from inpatient and outpatient settings, must be ≥18 years old, with type 1 or 2 diabetes and a Grade I-C or II-C DFU (Lavery et al, 1996). Other inclusion criteria include HbA<sub>1c</sub> ≤10% (≤86mmol/mol) and ulcer surface area 1–30cm<sup>2</sup> after debridement. DFUs with and without peripheral arterial disease will be included.

## Interventions

Following a 2-week run-in period, participants will be randomised to receive either UrgoStart® Contact or a neutral contact-layer dressing (Urgotul®). This will follow a centralised randomisation list and be stratified according to wound size (1–5cm<sup>2</sup> and 5–30cm<sup>2</sup>), a known prognostic marker of wound healing (Zimny et al, 2002). The two dressings are identical in appearance and packaging and therefore suitable for a double-blind trial.

Dressings will be changed every 2 days, unless clinical factors (such as exudate level) dictate otherwise. Local wound management will follow international guidelines (Bakker et al, 2012) with standard debridement when appropriate. Hyperkeratosis will be removed. Further detailed assessments following standard procedures will be undertaken at weeks 2, 4, 8, 12, 16, and 20. At week 20, or on documented full healing, patients will undergo a 12-week follow-up.

## Outcomes

The primary endpoint is complete wound closure, defined as 100% epithelialisation with no drainage. Secondary endpoints include time to wound healing, tolerability, occurrence of local adverse events, and quality of life in relation to the dressing.

## Ethics

The trial will follow European good clinical practice recommendations. Participants

will be briefed appropriately on the study objectives, potential contraindications, and benefits, and informed, written consent will be required to participate.

## CONCLUSION

There is a lack of firm evidence for the efficacy of dressings in the local management of DFUs. The Explorer study is designed to make a major contribution to the evidence base in this field. It will assess UrgoStart® Contact in an RCT on a mixed population of relatively large DFUs with the clinically relevant endpoint of wound closure. As such, it will bring a much-needed element of clinical rigour to the decision-making process in this challenging arena. **WUK**

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