

RCT on Bioactive Glass S53P4 in Diabetic Foot Osteomyelitis in the Forefoot (DFORCT)

NCT06388603

Status	RECRUITING
Phase	Not Applicable
Sponsor	ASST Ovest Milanese
Enrollment	140 participants

Key Eligibility Criteria

Inclusion (7)

- Written informed consent obtained.
- Male or female patients \geq of 18 years old.
- They should have type I since at least 5 years or type II DM
- They should have a diagnosis - confirmed by imaging and culture - of OM localized in the forefoot not responding for at least 2 up to 6 weeks to systemic antibiotic therapy and/or associated with soft tissue infection, abscess, phlegmon, necrosis, and for which a surgical debridement is indicated.
- They should have palpable pulses on TP or DP at the ankle in the affected limb, and/or ABPI >0.7 and <1.2 and /or TcPO₂ at dorsum of the foot ≥ 36 mmHg.

... and 2 more (see full listing online)

Exclusion (13)

- They should not have metabolic decompensation as witnessed by HbA_{1c} >109 mmol/mol ($> 12\%$).
- They should not have major amputation on the contra-lateral limb.
- They should not have acute or chronic Charcot's foot in the affected foot.
- They should not have undergone surgical or endovascular revascularization in the affected foot in the month preceding the enrollment.
- They should not be taking corticosteroids, bisphosphonates, immunosuppressants, and more in general any drug which might interfere with bone metabolism or tissue repair, in the judgment of investigators.

... and 8 more (see full listing online)

Locations (7 total)

ASUGI Azienda Sanitaria Universitaria Giuliano Isontina - Ospedale Monfalcone, Monfalcone, Gorizia, Italy

ASST Ovest Milanese - Ospedale di Abbiategrasso, Abbiategrasso, Milano, Italy

Casa di Cura Abano Terme - POLICLINICO ABANO TERME, Abano Terme, Padova, Italy

... and 4 more locations