ZABAS Trial – Summary of Results (EudraCT 2019-001650-26)

Zoledronic acid for prevention of bone loss after bariatric surgery

Study design

Randomised, placebo-controlled, double-blind, investigator-initiated clinical trial performed at the University Hospital of Southern Denmark, Esbjerg. Adults scheduled for bariatric surgery were randomized 1:1 to receive a single intravenous infusion of zoledronic acid (5 mg) or placebo prior to surgery. Follow-up was 12 months postoperatively.

Participants

	Zoledronic acid	Placebo	Total
N randomized	31	28	59

Participants underwent Roux-en-Y gastric bypass or sleeve gastrectomy according to standard clinical practice.

Intervention

A single 5 mg dose of zoledronic acid was administered intravenously 7–180 days prior to surgery (planned window 7–59 days). All participants received standard postoperative care including vitamin D and calcium supplementation.

Primary aim (bone)

To determine whether a single dose of zoledronic acid prevents postoperative loss of bone mass following bariatric surgery.

Key bone outcomes

At 12 months:

- Zoledronic acid **increased lumbar spine BMD** compared with placebo.
- Hip bone mineral density loss was **reduced** in the zoledronic acid group.
- Bone turnover markers were partially suppressed.

Interpretation: Zoledronic acid mitigated bone loss after bariatric surgery and was well tolerated.

Secondary aim (muscle)

To evaluate whether zoledronic acid prevented loss of lean mass, muscle strength, and physical function.

Key muscle outcomes

At 12 months:

- Both groups lost ~14% lean body mass
- Absolute lower-limb strength declined similarly in both groups
- Relative strength and physical function improved similarly in both groups
- No clinically relevant between-group differences were observed

Interpretation: Zoledronic acid **did not prevent muscle loss or muscle strength declines**.

Safety

Treatment was well tolerated with no unexpected adverse events. Flu-like symptoms occurred in both groups (zoledronic acid and placebo). No serious adverse events were attributed to study medication.

Conclusions

A single pre-operative infusion of 5 mg zoledronic acid **prevented postoperative bone loss** in patients undergoing bariatric surgery, particularly at the lumbar spine and hip. However, zoledronic acid **did not prevent loss of lean mass, muscle strength, or physical function.** The treatment was safe and well tolerated.

Trial registration

EudraCT: 2019-001650-26
ClinicalTrials.gov: NCT04742010

Sponsor

University Hospital of Southern Denmark
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