STANDARD OPERATING PROCEDURE

Department:	**Orthogeriatric / Trauma and Orthopaedics**
SOP Ref No:	**1:0**
SOP Title:	**Bone Protection Post Low Trauma Fractured Neck of Femur**

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CHANGE/AMENDMENT HISTORY:

Record of changes: (latest version number to be listed first)

Version No	Effective Date	Brief Summary of Changes	Author
Version 1		• This is a new procedural document, please read in full.	Rowan Barrass

1 INTRODUCTION

The purpose of this SOP is to update clinical practice based on the latest evidence regarding bone protection following a low-trauma* neck of femur fracture.

One of the key issues addressed in this SOP is the timing of IV zoledronic acid administration post operatively.
The previous established practice at Doncaster Royal Infirmary (DRI) has been to delay administration of zoledronic acid until day 10 post-op because of historical concerns about efficacy, delayed fracture healing and potential non-union. (This practise in itself has been off license use as licencing is for two weeks post operatively, however, it followed local services practice).
Consequently, patients that have been discharged from DRI prior to day 10 post surgery have not received zoledronic acid (and the associated reduction in fracture risk) before leaving hospital.
The latest evidence including systematic reviews and meta-analyses of early post-surgery administration (10 studies, totalling 2,888 patients), show bone mineral density gains over 12 months, with no evidence of non-union or delayed radiological or clinical fracture healing. Therefore, this SOP intends for all suitable patients to receive zoledronic acid before leaving hospital based on the latest available evidence[1].

*Low trauma is defined for the purpose of this SOP as a fracture resulting from a fall from standing height or less, or from an equivalent minimal force that would not normally cause a fracture in healthy bone.

Key Points:

- A quarter of people will break another bone within 5 years after a hip fracture[1].
- Zoledronic acid can reduce the risk of re-fracture by a third in this population[1].
- According to The National Osteoporosis Guideline Group (NOGG), patients should be offered intravenous zoledronate as a first-line treatment option following a hip fracture[3].
- Protocols to provide this treatment before patients leave hospital should be a standard of care[1].

2 ROLES AND RESPONSIBILITIES

- **Orthogeriatricians** –
    - Aim to review all inpatients over 60 years with low-trauma neck of femur (NOF) fractures within 72 hours of admission.
    - Ensure patient not already receiving bone protection on admission.
- **Resident Doctors and Advanced Practitioners (APs)** –
    - Request all relevant baseline blood tests, including serum adjusted calcium, vitamin D, and renal function.
    - If patient is already receiving bone protection on admission (including alendronic acid, risedronate, denosumab, romosozumab and teriparatide) then highlight to Orthogeriatricians.

- Prescribe vitamin D (colecalciferol) loading and maintenance in accordance with this SOP.
- Review oral intake and consider intravenous fluids before zoledronic acid administration if CrCl is 30-35ml/min as per flow chart.
- If appropriate prescribe the zoledronic acid after performing creatinine clearance and vitamin D replacement where needed as per the flow chart below.
- Document decisions and treatment plans clearly in patient records.
- Inform nursing staff of prescription to enable ordering of medication.
- Ask GP to repeat serum adjusted calcium testing 4-6 weeks after completion of vitamin D loading to exclude possible unmasking of primary hyperparathyroidism.

- **Pharmacy** –
  - Verify vitamin D loading regimen and zoledronic acid prescription for appropriateness and dose.
  - Confirm renal function calculations and highlight any contraindications to the clinical team.
  - Ensure product availability and advise on administration timing in relation to vitamin D loading.
  - Ensure documented on EPMA of administration of zoledronic acid.
- **Nursing Staff** –
  - Administer vitamin D loading doses and prepare the patient for infusion.
  - Ensure drug ordered to administer when prescribed
  - Administer zoledronic acid over 30 minutes for all patients.
  - Monitor the patient during and after infusion for acute-phase reactions and escalate if required.

3 SPECIFIC STANDARD OPERATING PROCEDURE

3.1 Eligibility

- Adult inpatients who are 60 years and above with low-trauma neck of femur fracture.

3.2 Pre-infusion requirements

1. Calcium

- Check serum adjusted calcium before vitamin D loading and zoledronic acid infusion.
- If hypercalcemia, highlight to the Orthogeriatric team for further evaluation.
- If hypocalcaemia, highlight to Orthogeriatric team for further evaluation and replacement prior to zoledronic acid administration.
- Patients who are loaded with Vitamin D replacement require serum adjusted calcium to be rechecked in 4-6 weeks because this may unmask primary hyperparathyroidism.

2. Vitamin D loading–

- If Vitamin D <50 nmol/L or unknown* then give **Colecalciferol 50,000 IU daily over 5 days** (a minimum total of 150,000 IU required prior to zoledronic acid administration), followed by Calci-D one tablet once daily (or equivalent).
- **If vitamin D status is unknown and the serum adjusted calcium level is normal, any risks of empirical high-dose vitamin D loading are outweighed by the benefit of allowing zoledronic acid to be given promptly as an inpatient*[1].
- If Vitamin D >50 nmol/L then start Calci-D one tablet once daily (or equivalent).

3. Renal function – Calculate creatinine clearance (CrCl) using Cockcroft–Gault.

- Do not give zoledronic acid if CrCl <30 mL/min.
- If CrCl 30–35 mL/min, then Orthogeriatric team will consider on a case-by-case basis as per flowchart. This will require discussion with patient or family to explain this would be "off license" use given on a risk / benefit basis following the latest clinical evidence available[1].
- To be given over ≥30 min if CrCl <50 mL/min.

4. Hydration – Ensure patient is adequately hydrated; consider omitting or reducing diuretics on infusion day.

3.3 Timing (post-operatively)

- Give zoledronic acid before discharge once a minimum of 150,000 IU vitamin D has been administered and renal function stable as per flowchart.

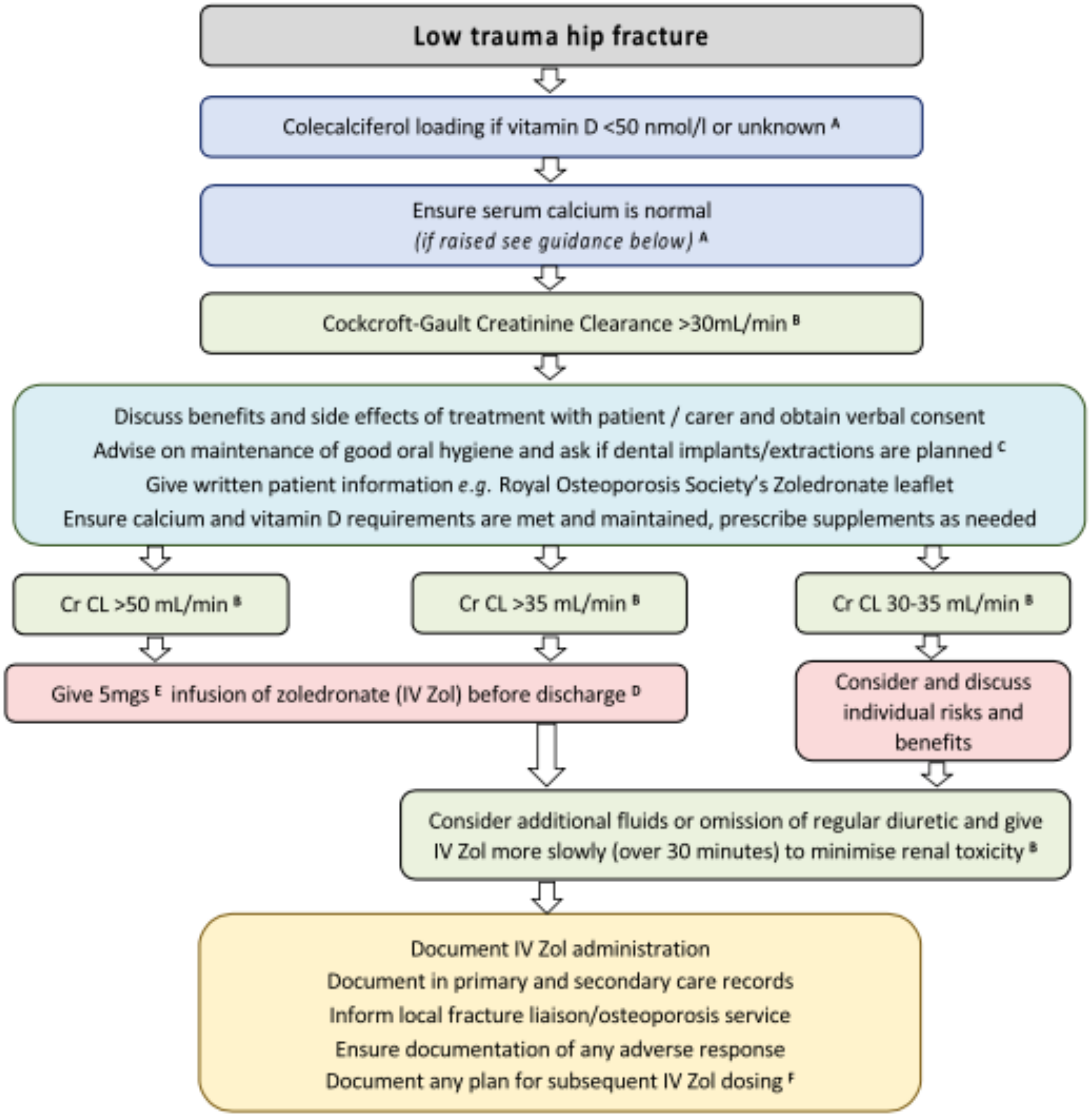
3.4 Timing (of administration)

- Recommended infusion time is between 15-30 minutes depending on renal function.
- For consistency zoledronic acid to be given over **30 minutes for all patients**.

3.5 Follow Up

- If already on treatment for bone health or under a specialist clinic then Orthogeriatric team to review need for further follow up.
- If patient age < 75 years then offer OP DEXA scan if appropriate. This will be interpreted by a Specialist who will then review the bone health plan and consider for further outpatient follow up if needed.
- If patient age > 75 years and clinically appropriate for further outpatient follow up in bone health clinic to consider for further doses of zoledronic acid or alternative treatment options (eg. Denosumab) then complete an outpatient referral (without DEXA scan).
- If patient has significant frailty or limited overall prognosis then consider for one off zoledronic acid with no further follow up.
- Document on discharge letter administration of zoledronic acid to prevent repeated doses within 12 months.

Flow Chart for intravenous zoledronate after hip fracture[1]



Summary of evidence for Flow Chart[1]

A: Vitamin D status and vitamin D loading regimes

Expert group consensus[1]: Many patients with hip fracture are vitamin D deficient. If vitamin D status is unknown and the serum calcium level is normal, any risks of empirical high-dose vitamin D loading are outweighed by the benefit of allowing IV zoledronic acid to be given promptly as an inpatient. **Hence, a loading regime of 150,000–250,000 IU, given in 'split' doses over 1–7 days, is appropriate.** The risk of missing a single large dose (for instance, if a patient is 'nil by mouth', delirious or vomiting or if lost tablets or spillages mean the drug is erroneously recorded as having been taken) can be minimised by 'splitting' loading doses. The prescribed vitamin D must be taken before IV zoledronic acid is administered.

If serum calcium is high on admission, high dose vitamin D supplementation should be avoided whilst the hypercalcaemia is investigated since, rarely, vitamin D loading may unmask previously undiagnosed primary hyperparathyroidism. **Patients with a baseline**

calcium at the upper end of normal (≥2.5mmol/l) should have a follow-up serum calcium test 4–6 weeks after vitamin D loading (IV zoledronic acid administration need not wait for this follow up test). If serum calcium is normal on admission, or initial hypocalcaemia resolves with vitamin D loading, then further testing is not needed.

B: Renal function and the safety, dose, and speed of zoledronate infusions

Expert group consensus[1]: Assessment of renal function should be based on a calculated CrCl (Creatinine Clearance). IV zoledronic acid should not be given when CrCl is <30ml/min. Although there are few data, IV zoledronic acid appears safe when CrCl is as low as 30–35ml/min and may be a treatment option on a case-by-case basis, with due precautions. IV zoledronic acid should be given over at least 30 min when CrCl is <50ml/min.

C: Dental issues and low risk of osteonecrosis of the jaw (ONJ)

Expert group consensus[1]: For patients with hip fracture, the absolute risk of imminent fragility fractures and the clear benefits of IV zoledronic acid usually far outweigh any potential risk of ONJ. Dental considerations should not limit the use of IV zoledronic acid; **patients should be informed of the very rare risk of ONJ and be encouraged to maintain good oral hygiene**.

D: Timing of infusion, need to wait 2 weeks and risk of non-union

Expert group consensus[1]: Systematic reviews and meta-analyses of **early post-surgery administration** (10 studies, totalling 2,888 patients), **show bone mineral density gains over 12 months, with no evidence of non-union or delayed radiological or clinical fracture healing.** Patients with hip fracture are at very high imminent re-fracture risk making it **important that they receive IV zoledronic acid before they are discharged**, so long as vitamin D replacement is complete and renal function has stabilised after surgery.

E: How big a dose of IV zoledronic acid is needed?

Expert group consensus[1]: The original trial of IV zoledronic acid after hip fracture used annual doses of 5mg, but subsequent studies have shown similar effects on bone biochemistry with lower doses. The less expensive 4mg formulation is an alternative if health resources are constrained or the 5mg formulation is not accessible. The 4mg dose is unlicensed and should be discussed on a case by case situation with orthogeriatricians and patient/next of kin.

F: How often does IV zoledronic acid need to be given?

Expert group consensus[1]: The first dose of IV zoledronic acid is the most important to offer to inpatients. Further doses at 12–18 month intervals carry additional benefit and should be arranged, unless individual patients' frailty at the time of discharge suggests that this will not be beneficial or feasible. **Local community services need to innovate to enable practical solutions to subsequent dosing.**

4 ASSOCIATED TRUST PROCEDURAL DOCUMENTS/FORMS/ TEMPLATES TO BE USED

External references

1. Johansen A. et al., *Call to action: a five nations consensus on the use of intravenous zoledronate after hip fracture*, Age and Ageing, 2023

2. Zoledronic acid 5 mg solution for infusion - Summary of Product Characteristics (SmPC) - (emc) | 5242
3. National Osteoporosis Guideline Group. (2024). Clinical guideline for the prevention and treatment of osteoporosis. Updated Decemeber 2024 www.nogg.org.uk

Internal documents

2. Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust. *Medicines Formulary, Section 6.6 – Calcium and Vitamin D Preparations*. Approved January 2022, review due January 2025. Available at: https://www.dbth.nhs.uk/wp-content/uploads/2022/01/Section-6.6.pdf