A interventional study in a real life setting to assess the clinical efficacy and effect to fracture in the 1 year after the injection of zoledronic acid in osteoporotic patients with long bone or spine, pelvic fractures

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Introduction

Zoledronate

- Oral bisphosphonate has gastrointestinal side effect, and low compliance. Zoledronate provide an alternative for patients who cannot tolerate oral bisphosphonate.

- HORIZON-PFT trial (7765 postmenopausal women)
  Once-yearly infusion of zoledronic acid during 3 year significantly reduced the incidence of vertebral, hip, and non-vertebral fracture.
Introduction

To investigate

- **The change in bone mineral density (BMD)**
- **Change in back pain (VAS)**
- **Fracture healing**
- **Newly developed fracture**
- **Adverse effect**

in elderly postmenopausal osteoporosis patients who has had vertebral fracture or non-vertebral fracture treated with zoledronate
Zoledronate injection

- IV zoledronate (Aclasta®, 5mg/100ml)
- 1 time injection
- 3 days after the fracture diagnosed

Exclusion: patients who has contraindications of IV zoledronate fracture not related with osteoporosis

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- Postmenopausal women who had osteoporosis (T score < -2.5)
- with osteoporotic vertebral fracture or non-vertebral fracture
- who approved the informed consent

Materials & Methods

Safety assessment

- Adverse events

Efficacy assessment

- BMD
- Change of back pain
- Healing status of fracture
- Newly developed fracture
253 Patients

- 10 patients are excluded
  - 8 has chronic renal failure
  - 2 has hypocalcemia

243 Patients

- 115 lost to follow-up

Vertebral fracture
97 patients

Non-vertebral fracture
31 patients

ITT analysis for safety assessment

Efficacy assessment
## Study groups (N=130)

**Mean age (yrs.) = 71.1 ± 9.1**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12 months after Zoledronate injection</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vertebra T-score</strong></td>
<td>-3.00 ±0.77</td>
<td>-2.70 ±1.47</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td><strong>Femoral neck T-score</strong></td>
<td>-2.80 ±0.77</td>
<td>-2.70 ±0.87</td>
<td>P&lt;0.05</td>
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<tr>
<td><strong>Lowest T-score</strong></td>
<td>-3.40 ±0.70</td>
<td>-3.20 ±0.76</td>
<td>P&lt;0.05</td>
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Vertebral fracture group (N=97)

Mean age (yrs.) = 71.9 ± 9.4

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<tr>
<td>Vertebra T-score</td>
<td>-3.14 ±0.85</td>
<td>-2.76 ±1.61</td>
<td>P&lt;0.05</td>
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<tr>
<td>Femoral neck T-score</td>
<td>-2.92 ±0.84</td>
<td>-2.76 ±1.09</td>
<td>P&lt;0.05</td>
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<tr>
<td>Lowest T-score</td>
<td>-3.55 ±0.71</td>
<td>-3.30 ±0.79</td>
<td>P&lt;0.05</td>
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</table>
Results - BMD

Non-vertebral fracture group (N=31)

Mean age (yrs.) = 70.3 ± 8.5

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</thead>
<tbody>
<tr>
<td>Vertebra T-score</td>
<td>-2.85 ±1.03</td>
<td>-2.71 ±0.84</td>
<td>P&lt;0.05</td>
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<tr>
<td>Femoral neck T-score</td>
<td>-2.71 ±0.61</td>
<td>-2.66 ±1.01</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>Lowest T-score</td>
<td>-3.26 ±0.99</td>
<td>-2.94 ±0.80</td>
<td>P&lt;0.05</td>
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</tbody>
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Results - Fracture

- Delayed healing, Nonunion : 0 case

- New developed fracture : 3 cases
  - Vertebral fracture : 2 cases
  - Distal radius fracture : 1 case
Results – Adverse Effects

- **Reported side effects**: 11 cases (4.5%)
  - Flu-like symptom: 6 cases
  - Nausea/vomiting: 1 case
  - Dyspepsia: 1 case
  - Joint swelling: 1 case
  - Arthralgia: 1 case
  - Dizziness: 1 case
Conclusions

- Administration of zoledronate in postmenopausal osteoporosis patient who had vertebral fracture or non-vertebral fracture

  - Bone mineral density improvement
  - Reduced back pain
  - No influence on fracture healing

Zoledronate is effective treatment for osteoporosis of elderly postmenopausal patients who had vertebral fracture or non-vertebral fracture.