

# **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*

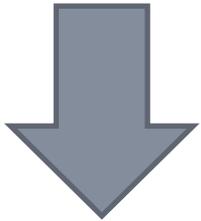
**in elderly postmenopausal osteoporosis patients who has had vertebral fracture or non-vertebral fracture treated with zoledronate**

# Materials & Methods



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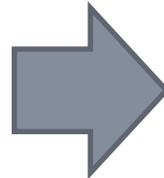
- Postmenopausal women who had osteoporosis (T score < -2.5)
- with osteoporotic vertebral fracture or non-vertebral fracture
- who approved the informed consent



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

## **Zoledronate injection**

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



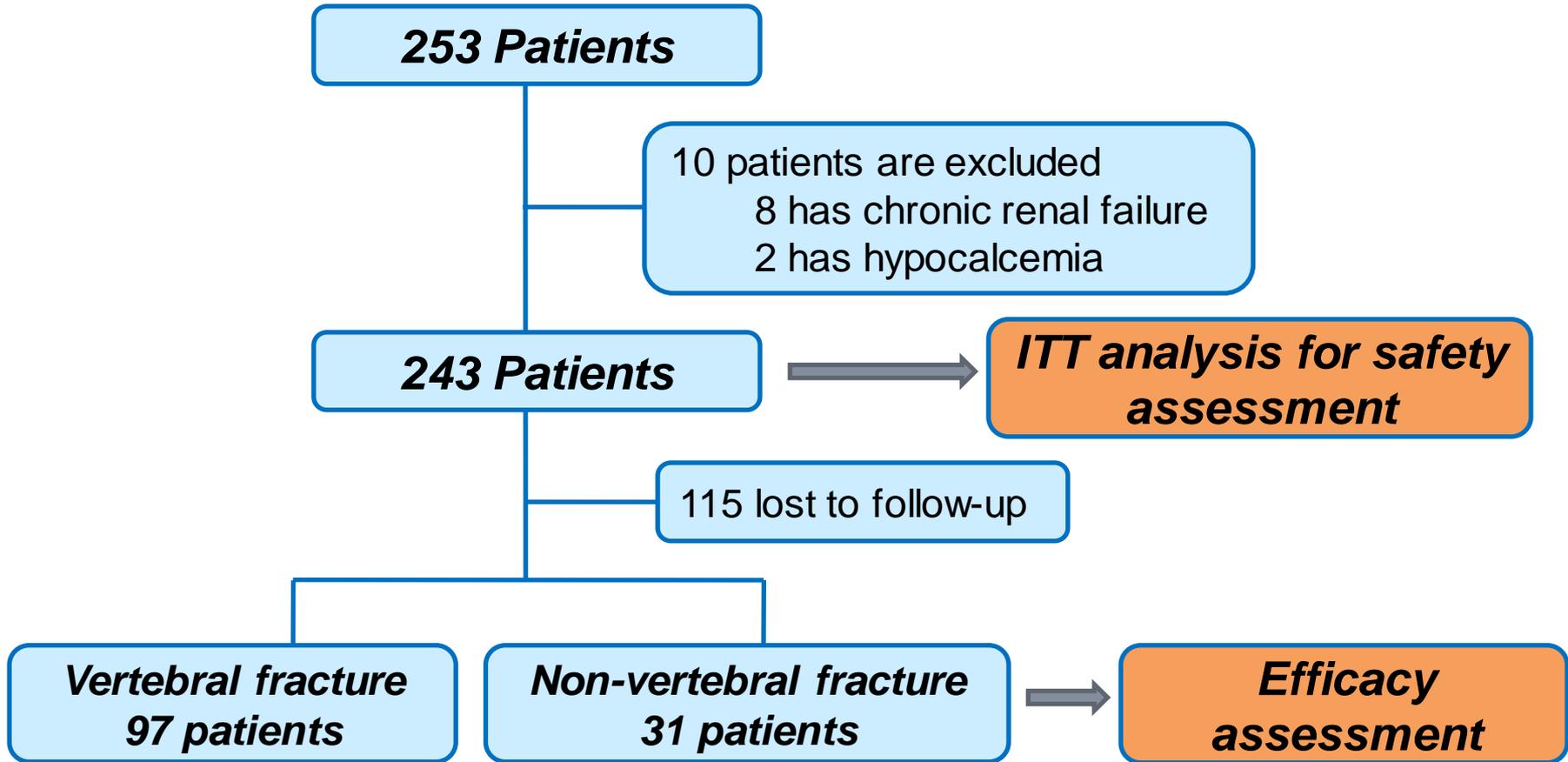
## **Safety assessment**

- Adverse events

## **Efficacy assessment**

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

# Materials & Methods



# Results - BMD



*Study groups (N=130)*

*Mean age (yrs.) = 71.1 ± 9.1*

	<i>Baseline</i>	<i>12 months after Zoledronate injection</i>	<i>P-value</i>
<i>Vertebra T-score</i>	<i>-3.00 ±0.77</i>	<i>-2.70 ±1.47</i>	<i>P&lt;0.05</i>
<i>Femoral neck T-score</i>	<i>-2.80 ±0.77</i>	<i>-2.70 ±0.87</i>	<i>P&lt;0.05</i>
<i>Lowest T-score</i>	<i>-3.40 ±0.70</i>	<i>-3.20 ±0.76</i>	<i>P&lt;0.05</i>

# Results - BMD



## *Vertebral fracture group (N=97)*

*Mean age (yrs.) = 71.9 ± 9.4*

	<i>Baseline</i>	<i>12 months after Zoledronate injection</i>	<i>P-value</i>
<i>Vertebra T-score</i>	<i>-3.14 ±0.85</i>	<i>-2.76 ±1.61</i>	<i>P&lt;0.05</i>
<i>Femoral neck T-score</i>	<i>-2.92 ±0.84</i>	<i>-2.76 ±1.09</i>	<i>P&lt;0.05</i>
<i>Lowest T-score</i>	<i>-3.55 ±0.71</i>	<i>-3.30 ±0.79</i>	<i>P&lt;0.05</i>

# Results - BMD



## *Non-vertebral fracture group (N=31)*

*Mean age (yrs.) = 70.3 ± 8.5*

	<i>Baseline</i>	<i>12 months after zoledronate injection</i>	<i>P-value</i>
<i>Vertebra T-score</i>	<i>-2.85 ±1.03</i>	<i>-2.71 ±0.84</i>	<i>P&lt;0.05</i>
<i>Femoral neck T-score</i>	<i>-2.71 ±0.61</i>	<i>-2.66 ±1.01</i>	<i>P&lt;0.05</i>
<i>Lowest T-score</i>	<i>-3.26 ±0.99</i>	<i>-2.94 ±0.80</i>	<i>P&lt;0.05</i>

# 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*

❖ ***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.**