

# This is a randomised study to assess the safety and efficacy of a combined drug and orthopaedic standard care compared to the standard orthopaedic care and treatment for Perthes Disease in children.

ACTRN12610000407099

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	The Royal Alexandria Hospital for Children
<b>Enrollment</b>	140 participants

## Plain Language Summary

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This trial is studying whether a bone-strengthening drug called zoledronic acid, given by IV, can help children and young adolescents with Perthes disease — a condition where the ball of the hip joint (femoral head) loses its blood supply and collapses. The hope is that the drug will slow or prevent the collapse of the bone, leading to a better-shaped hip joint and less pain. Participants will receive either zoledronic acid or standard care alone for 12 months.

You may be eligible if:

- Your child has been diagnosed with unilateral Perthes disease within the past 6 months
- Your child is between 5 and 16 years old
- The affected bone still has more than 50% of its structure compared to the other side

You may NOT be eligible if:

- The hip bone loss is not due to Perthes disease
- Your child has received bisphosphonate treatment before
- Your child is pregnant or sexually active without using contraception
- Your child has untreated rickets within the past year
- Your child takes certain medications (e.g., steroids, growth hormone, anticonvulsants, calcitriol)
- Your child has abnormal liver, thyroid, vitamin D, or kidney function

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (1)

- Diagnosis of unilateral Perthes Disease within the preceding 6 months and with lateral pillar >50% of the contralateral side at the time of enrolment.

### Exclusion (7)

- Diagnosis of Avascular Necrosis of the femoral head not due to Perthes Disease.
- Previous treatment of bisphosphonates.
- Current pregnancy or sexually active and not using a medically acceptable form of birth control.
- Untreated rickets within 1 year of enrolment.
- History of clinically significant organic or psychiatric findings on physical examination, which in the opinion of the investigator would prevent the patient from completing the study.

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

## Locations (1 total)

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12610000407099>  
Auckland, New Zealand

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