

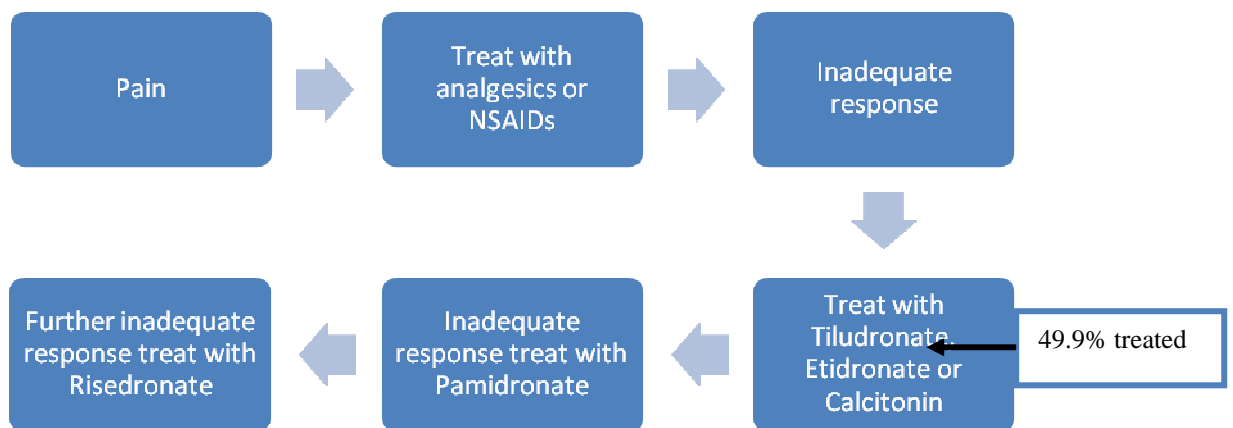
PRISM STUDY

RANDOMISED TRIAL OF INTENSIVE BISPHOSPHONATE TREATMENT VERSUS SYMPTOMATIC MANAGEMENT IN PAGET'S DISEASE OF BONE

This study which recruited 1,324 patients with Paget's disease was performed in 39 different centres in the UK with patients being followed up for a median of 3 years (range 2-5). The study was designed to compare the effects of two management strategies on fractures, quality of life, bodily pain, hearing loss and requirement for orthopaedic surgery.

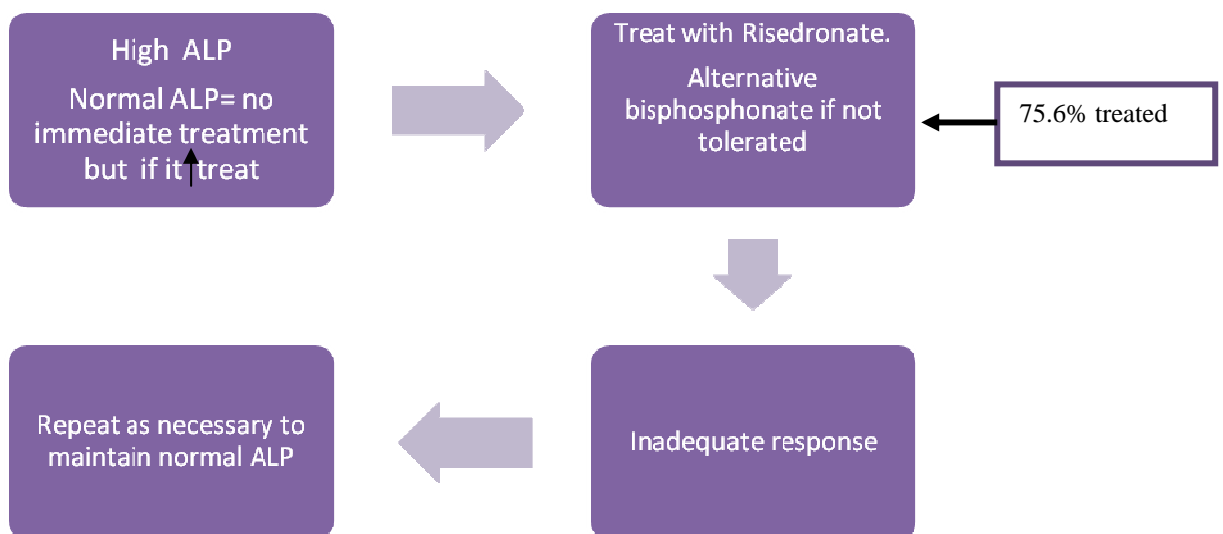
Following randomisation patients were allocated to either a symptomatic or intensive group for ongoing management of their Paget's disease

SYMPTOMATIC GROUP: TREATED ON BASIS OF PAIN



ONLY

INTENSIVE GROUP: TREATED ON BASIS OF ELEVATED ALP



RESULTS

- Alkaline Phosphatase (ALP)
 - Intensive group: Significant reduction in ALP within 4 m, and throughout study
 - Symptomatic group: Significant reduction in ALP from 12m
- Quality of Life
 - No difference between groups with respect to physical summary score, mental summary score and bodily pain
- Fracture rate and need for orthopaedic surgery
 - No difference between groups
- Hearing loss
 - Hearing thresholds remained stable with no difference between groups
- Bone pain
 - The proportion of patients with bone pain attributed to Paget's disease fell significantly between baseline and follow up at 2years, with no difference between the groups
- Non pagetic bone pain
 - Increased frequency of non pagetic bone pain in both groups

CONCLUSIONS

- Maintaining normal ALP levels with intensive bisphosphonate therapy, licensed at time of study, confers no advantage over symptom driven management in patients with established Paget's disease.
- Both strategies offered limited impact on quality of life, hearing loss and pain.
- Highlights the need for further studies to evaluate whether the significant effects of bisphosphonates on bone turnover can be translated into clinical benefits for patients.

FULL DETAILS

Langston AL, Campbell MK, Fraser WD, MacLennan GS, Selby PL, Ralston SH for the PRISM Trial Group 2009. Randomised trial of intensive

bisphosphonate treatment versus symptomatic management in Paget's disease of bone. *J Bone Miner Res.* Jul 6 (Epub ahead of print).