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Title: Does adjuvant zoledronic acid reduce recurrence in patients with high risk localized breast cancer? – The AZURE Trial.
BIG 1-04

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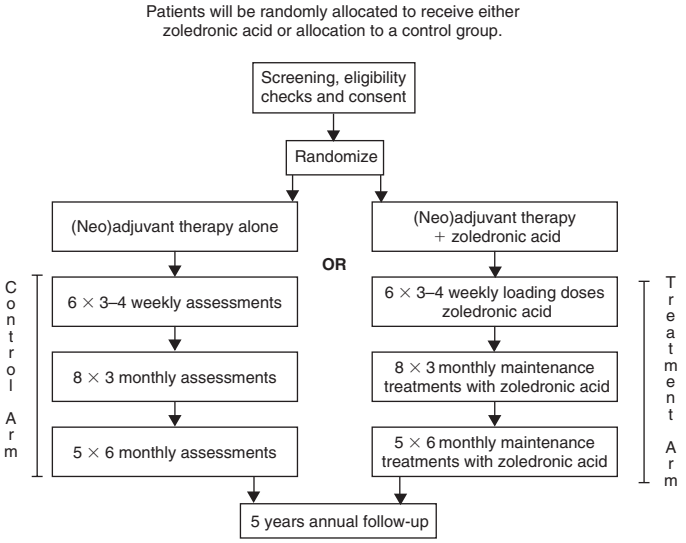
Summary:

- Recruitment closed in January 2006
- Total of 3360 patients recruited

Objective:

- It is the aim of this prospective, randomized, open label, parallel group trial to determine whether adjuvant treatment with 4 mg zoledronic acid with (neo)adjuvant chemotherapy and/or adjuvant hormonal therapy is superior to (neo)adjuvant chemotherapy and/or adjuvant hormonal therapy alone in improving the disease-free and bone metastasis-free survival of stage II/III breast cancer patients.

Scheme:



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Update:

- The AZURE trial closed to recruitment on the 20th January 2006, having reached target recruitment 8 months ahead of schedule. A total of 3360 patients have been recruited from 174 sites internationally including sites in Spain, Portugal, Ireland, Australia, Thailand and Taiwan.

Related Publications: No publications as yet.

Topics:

- Bisphosphonates
- Locally advanced breast cancer
- Node positive breast cancer

Keywords: Zoledronic Acid, high risk, localized breast cancer, adjuvant, bisphosphonates

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Title: Cost-effective use of *BIS*phosphonates in metastatic bone disease: A comparison of bone *MARK*er directed zoledronic acid therapy to a standard schedule – The BISMARK Trial.

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Summary:

- It is the aim of this trial to determine whether a bone marker directed schedule of bisphosphonate therapy is comparable with a fixed 3–4 weekly strategy in preventing skeletal related events and maintaining quality of life.

Primary Objective:

- To compare the frequency and timing of all SREs. These are defined as fractures, radiotherapy to bone, hypercalcaemia of malignancy, orthopaedic surgery and spinal cord compression.

Secondary Objectives:

To compare:

- Quality of life (QoL).
- Clinical burden of skeletal complications.
- Pain, performance status and analgesic use (PPA score).
- The incidence of new bone metastases.
- Overall survival.
- Bisphosphonate use and expenditure on administration.

Sub-studies in a sub-set of the study population will compare:

- Health care utilisation.
- Evaluation of the clinical utility of the "point of care" test for Ntx excretion.
- Changes in serum markers of bone metabolism.

The trial recruited its first patient in March 2006 and aims to recruit 1500 patients over a 2–3 year period.

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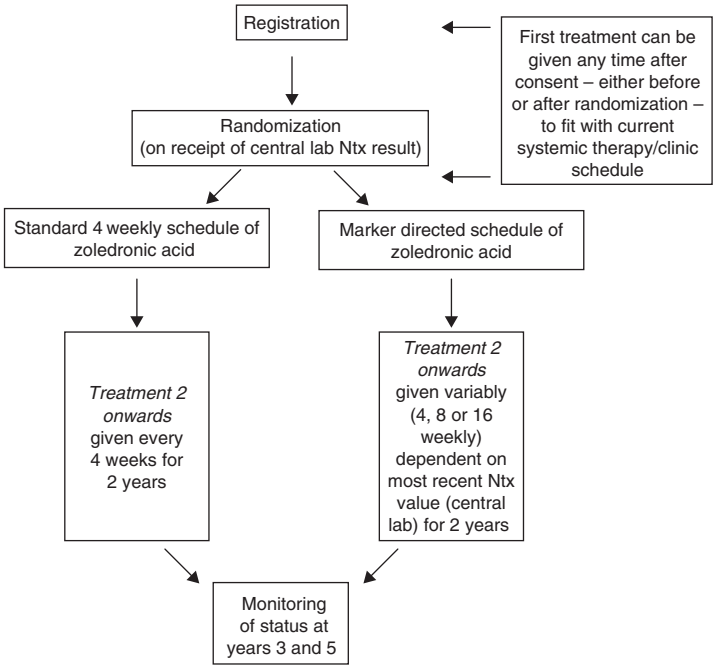
Scheme:



Update:

- 21 centres are open to recruitment, 49 patients have been randomised to date 6 October 2006. Protocol version 3.0 was approved at the end of September 2006. Major changes are:
  1 inclusion of patients with a minimum of 4 months prior Zometa treatment and a maximum of 12 months prior bisphosphonates.
  2 Novartis support for the trial, including investigator payments.

Related Publications: None available

Topics:

- Bisphosphonates
- Blood markers
- Metastatic breast cancer
- Predictive markers
- Prognostic factors

Keywords: Bisphosphonates, urinary Ntx, bone markers, metastatic breast cancer

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