

SWOG S0702: A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients With Bone Metastasis Starting Zoledronic Acid Treatment

Fast Facts

Eligibility Criteria

1. Participant must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease.
2. All participants must be planning to receive zoledronic acid (as their sole bisphosphonate therapy) within 30 days after registration. (NOTE: Bisphosphonate therapy will continue thereafter as clinically indicated.) Patients previously treated with bisphosphonate therapy are eligible if the following criteria apply:
 - a. Patients may have previously received at most 3 doses of intravenous bisphosphonate therapy with ibandronate, pamidronate or zoledronic acid for low bone mass (osteopenia or osteoporosis) within 3 years prior to registration or
 - b. Patients may have received intravenous bisphosphonate therapy with ibandronate, pamidronate or zoledronic acid to treat metastatic bone disease within 90 days prior to registration. Patients receiving any of these regimens for metastatic bone disease prior to 90 days before registration are not eligible, or
 - c. Prior oral bisphosphonate therapy at any time prior to registration is allowed.

NOTE: the sum of IV bisphosphonate doses in “a” and “b” above must not be greater than 4
3. Participants must not have a pre-existing diagnosis of ONJ.
4. Participants must not have a history of radiation to the maxillofacial area administered for therapeutic intent in the treatment of cancer.
5. Participants must have a Zubrod performance status of 0-3 (see Section 10.2).
NOTE: Participants who may be acutely ill from spinal cord compromise, hypercalcemia of malignancy or other process may be study candidates once the acute condition has been addressed and performance status improves to 0-3.
6. Participants must be willing and physically able to comply with the study procedures and assessments.
7. Patients must be offered the option to submit blood for banking and DNA analysis, as specified in Section 15.0.
8. Participants must be willing to provide information on history, including tobacco and alcohol use, symptoms, and pain assessment.
9. Patients are required to undergo a baseline dental exam. The dental exam must occur within 6 months prior to registration. The baseline dental exam is to include: dental history, dental exam, periodontal exam and dental imaging. Panoramic x-ray is the preferred imaging technique, although other imaging modalities such as intraoral films (small films), bite wings, x-rays films and/or digital files may be appropriate for some individuals. Dental imaging within 12 months prior to registration is acceptable. The **S0702** Dentist Contact Form and **S0702** Dental Assessment Form (related to the baseline dental exam) must be completed by the Dental Health Professional and returned to the registering institution prior to registration.
10. Participants must be willing to provide access to prior and future dental information.
11. Participants can concurrently participate in other therapeutic and non-therapeutic clinical trials.
12. No other prior malignancy is allowed except for the following: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease-free for 5 years.
If the patient has had multiple tumors of the same basic origin, this may be counted as one malignancy. E.g. breast cancer (bilateral disease or multiple lesions), head and neck cancer (tongue and laryngeal).
13. All patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.
14. At the time of patient registration, the treating institution's name and ID number must be provided to the Data Operations Center in Seattle in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered into the data base.

Prestudy Parameters

1. History and physical
2. Dental exam, dental imaging
3. Labs including CBC with differential, CMP, pregnancy test (all are suggested for GCP)

Study Events

Every 6 months - History and physical and dental exam for three years or until ONJ diagnosis.

After ONJ diagnosis, dental exam every three months.