



Phase III and IV Development of the EORTC QLQ-BM22

EORTC meeting

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The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for patients with Bone Metastases: The EORTC QLQ-BM22

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Phase III - Pre-testing

- International collaborators
 - Argentina
 - Australia
 - Austria
 - Canada (including Quebec)
 - Germany
 - Greece
 - Hong Kong
 - Japan
 - Netherlands
 - Sri Lanka
 - UK
 - USA



Final EORTC QLQ-BM22 Questionnaire after Phase III

During the <u>past week</u> have you had <u>pain</u> in any of the following parts of your body?	Not at All	A Little	Quite a Bit	Very Much
1. in your back?	1	2	3	4
2. in your leg(s) or hip(s)?	1	2	3	4
3. in your arm(s) or shoulder(s)?	1	2	3	4
4. in your chest or rib(s)?	1	2	3	4
5. in your buttock(s) ?	1	2	3	4
During the <u>past week</u>:				
6. Have you had constant pain?	1	2	3	4
7. Have you had intermittent pain?	1	2	3	4
8. Have you had pain not relieved by pain medications?	1	2	3	4
9. Have you had pain while lying down?	1	2	3	4
10. Have you had pain while sitting?	1	2	3	4
11. Have you had pain when trying to stand up?	1	2	3	4



Final EORTC QLQ-BM22 Questionnaire after Phase III cont'd

12. Have you had pain while walking?		1	2	3	4
13. Have you had pain with activities such as bending or climbing stairs?		1	2	3	4
14. Have you had pain with strenuous activity (e.g. exercise, lifting)?		1	2	3	4
15. Has pain interfered with your sleeping at night?		1	2	3	4
16. Have you had to modify your daily activities because of your illness?		1	2	3	4
17. Have you felt isolated from those close to you (e.g. family, friends)?		1	2	3	4
18. Have you worried about loss of mobility because of your illness?		1	2	3	4
19. Have you worried about becoming dependent on others because of your illness?		1	2	3	4
20. Have you worried about your health in the future?		1	2	3	4
21. Have you felt hopeful your pain will get better?		1	2	3	4
22. Have you felt positive about your health?		1	2	3	4



Phase IV – Large-scale international field-testing

- Accrual has begun to test the reliability and validity of the module development Phase I - III
- Collaborators from: Argentina, Australia, Austria, Canada, Germany, Greece, Hong Kong, Japan, Netherlands, Sri Lanka, UK and USA



Phase IV Testing - Patient Groups

Group	Description – BM22
A	Patients receiving palliative radiotherapy or radiosurgery (RS)
B	Patients receiving a new bisphosphonate (e.g. pamidronate/clondronate/zoledronic acid) within the previous two weeks
C	Patients receiving a new systemic therapy (e.g. chemotherapy/hormone therapy) within the previous two weeks
D	Patients undergoing orthopaedic stabilization (impending or pathological fracture/spinal cord compression)
E	Patients undergoing minimally invasive procedures (e.g. vertebroplasty/cementoplasty/kyphoplasty)
F	Patients undergoing analgesic adjustments in pain and symptom management clinic
G	Patients with stable bone metastases not undergoing new treatment for at least two weeks (e.g. breast or prostate cancer patients with bone metastases)



Phase IV – Large-scale international field-testing

- At baseline, patients will complete:
 - Demographic/clinical data/current treatment information form
 - Analgesic intake form
 - C15-PAL
 - BM 22
 - Debriefing form
- Baseline assessment for:
 - Groups A-F will take place prior to their bone metastases-specific treatment
 - Group G will take place at clinic visit (no bone metastases specific treatment in previous two weeks)



Phase IV – Large-scale international field-testing

- At follow-up patients complete:
 - Follow-up form (KPS, SREs, change in systemic therapies, hospitalization, analgesic intake)
 - C15-PAL
 - BM 22
- Follow-up assessment for:
 - Groups A-F will take place one month following initiation of bone metastases specific treatment (ie. one month after radiation, systemic treatment, or surgery).
 - Group G will take place one week after baseline assessment to assess the *test-retest reproducibility* of the questionnaire



Phase IV – Large-scale international field-testing

- Statistical Analyses:
 - Multi-trait scaling
 - Reliability (test-retest reliability)
 - Correlation analyses with other instruments
 - Clinical validity ie. known group comparisons (sensitivity)
 - Responsiveness to change over time
 - A $p < 0.05$ will be considered statistically significant (alpha level for p value will be adjusted for multiple comparisons)



Thank You

Suggestions and Comments

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