Quality of Life Research in IBCSG Trials 24-26

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March 2003

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Quality of Life Objectives in Trials 24-26

- **Quality of Life will be described in regard to intermediate and long-term effects of treatment and disease (longitudinal design)**
- **The randomized treatments will be compared in regard to Quality of Life**
- **Particular emphasis on the treatment-related menopausal symptoms and their special impact on Quality of Life and on the course of patients' adaptation**

Quality of Life Approach in Trials 24-26

- **The young patients receiving adjuvant endocrine treatments are faced with menopausal symptoms**
- **This may have important impact on their quality of life (physically and emotionally)**
- **Symptoms may be associated with sleeping difficulties, feelings of depression, problems in sexuality and partnership etc.**

➡ **Quality of Life evaluation including menopausal symptoms is an essential objective in these trials**

The Quality of Life approach is the same for all 3 trials

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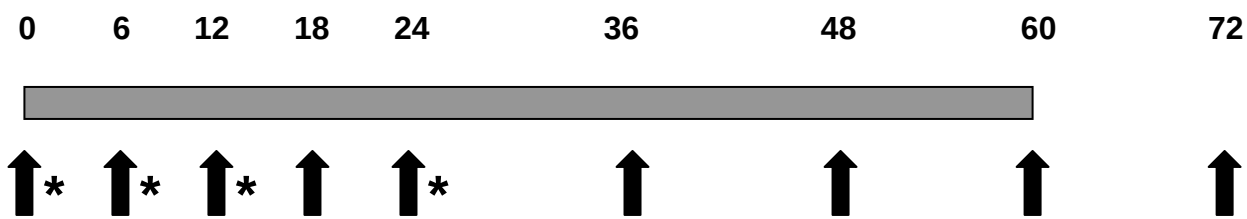
Quality of Life Study Design for Trials 24-26

Quality of Life Assessment Time Points

Months from Randomization



Tamoxifen for 5 years or
OFS plus Tamoxifen for 5 years (with or without Chemotherapy) or
OFS plus Exemestane for 5 years (with or without Chemotherapy)

QL Assessment: Core & Module

QL Assessment: Core & Module plus supplement for centers with English as primary language

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QL Primary Hypotheses in Trials 24-26

PERCHE (26-02)

Chemotherapy plus Ovarian Function Suppression plus Exemestane

leads to more menopausal symptoms (hot flushes) and sexual impairment (loss of sexual interest) than

Chemotherapy plus Ovarian Function Suppression plus Tamoxifen.

TEXT (25-02) and SOFT (24-02)

Ovarian Function Suppression plus Exemestane

leads to more menopausal symptoms (hot flushes) and sexual impairment (loss of sexual interest) than

Ovarian Function Suppression plus Tamoxifen

SOFT (24-02)

Ovarian Function Suppression plus Tamoxifen

leads to more menopausal symptoms (hot flushes) and sexual impairment (loss of sexual interest) than

Tamoxifen alone

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QL Secondary Hypotheses in Trials 24-26

We suppose that the differences between treatment arms will persist over the whole treatment period.

Those patients who report more severe menopausal symptoms during the first 6 months on study will also report delayed adaptation in other Quality of Life indicators both during and beyond that time.

„Physical well-being“, „Mood“ and „Coping“ will be used to describe patients‘ adaptation over time.

Quality of Life Questionnaires

Quality of Life Core Form (QLC):

Global and specific LASA indicators:

physical well-being, mood, coping, perceived social support, subjective health estimation, nausea/vomiting, tiredness, hot flushes, restrictions in arm movement

Quality of Life Module Form (QLM):

Focus on various treatment-related endocrine symptoms as sweats, vaginal problems, sleep disturbance, dizziness, headaches, weight gain etc.

Quality of Life Supplement Form (QLS):

In a supplementory study in centers with English as main language the sensitivity of selected IBCSG indicators for depression and sexual dysfunction will be investigated.

Why a Supplement QL Form for the English speaking centers only ?

This Supplement QL Form will help answering a methodological question about the validity of the LASA-scales used in the QL Modules concerning depression and sexuality.

Being able to answer this research question it is sufficient if we get the data from all the English speaking Centers, so we don‘t have to include all the participating Centers into these supplement QL Assessments.

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Month Number ☐☐

Assessment Number ☐☐

IBCSG Patient ID 2 4 ☐☐☐☐ (Study No. / Patient ID No.)

Patient Initials ☐☐☐☐ (f m fl sl — first, middle, first last, second last)

Patient's Date of Birth ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)

Date Form Completed ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)

Center Code ☐☐☐☐☐☐

Participating Center Name/Affiliate _____ Version No. 1 Language No. 0 1

QUALITY OF LIFE MODULE FOR TRIAL 24-02 (Form 24-QLM)

Patient Instructions: We would like to know how strongly you are affected by your illness and treatment. Please answer the following questions by **placing a vertical mark on the line** depending on how you assess yourself. (See the example on the Quality of Life Core Questionnaire.)

Your information will be treated as strictly confidential. Thank you for replying!

We are particularly interested in any treatment related difficulties you might be experiencing.

Within the last two weeks, how severe have the following problems been?

Being irritable	None _____	Severe
Sweats (including night sweats)	None _____	Severe
Vaginal discharge	None _____	Severe
Vaginal dryness	None _____	Severe
Vaginal itching / irritation	None _____	Severe
Sleep disturbance	None _____	Severe
Feeling dizzy	None _____	Severe
Headaches	None _____	Severe
Bone or joint pain	None _____	Severe
Troubled by weight gain	None _____	Severe
Loss of sexual interest	None _____	Severe
Overall, how much are you bothered by any treatment related difficulties?	Not at all _____	Severely

Have you been sexually active during the past six months? ☐ yes ☐ no

If yes:

Did you have difficulties in becoming aroused?	None _____	Severe

Please check that all questions are answered. Thank you!

QL Data Management Issues

- **QL is mandatory for IBCSG centers**
- **Non-IBCSG centers participating in the trials may take part in the QL study (center-by-center negotiation)**
- **QL research is demanding and needs a lot of financial and personal resources**
- **Good acceptance by patients and staff is essential for good compliance (problem of missing data)**
- **Timing of QL assessment is essential:**
  QL assessments must be done before any treatment procedures
- **Completeness of data in longitudinal assessment designs is essential**

Does it play a role whether the patient fills in a QL Form before starting a chemotherapy cycle or some days later ?

At day 1, the patients report better scores compared to some days before or some days after starting chemotherapy

The worse scores after starting treatment can be explained by short-term toxicity of chemotherapy

The better scores at day 1 – or the worse scores some days before, respectively – may be explained by patients‘ coping. Patients often do not show their anxiety at beginning of a treatment. They may do so some days before, when they do not have to undergo treatment immediately.

Tips for the QL Data Management

- **Instruct the patient carefully at the first assessment, give support if needed in understanding the task and the questions and the purpose of the trial (serial assessment)**
- **Check the completed questionnaire while the patient is still present in case of missed items. If you find some questions not answered ask the patient whether she left them by mistake or on purpose.**
- **Check if the header is filled out properly before faxing the completed QL form to the IBCSG Data Management Center by DataFax.**
- **If the questionnaire has not been filled out, please fill in the Missed QL Assessment Form and indicate the reason for not filling in the QL Forms.**
- **Fax the QL Forms to the DMC in proper time.**
- **Contact the IBCSG Coordinating Center or the DMC for questions!**