A phase II study of intensity modulated radiation therapy (IMRT) with chemotherapy for loco-regionally advanced nasopharyngeal cancer (NPC)

Purpose:

To evaluate efficacy and safety of IMRT with concurrent chemotherapy in patients with stage II-IVB nasopharyngeal cancer.

Primary endpoint：

3-yr overall survival

Secondary endpoints：

Grade 2 or greater dry mouth at 1 and 2 years after IMRT (CTCAE v. 4),

overall survival, progression-free survival, locoregional progression-free survival, adverse events, protocol compliance, pattern of failure

Treatment:

Radiotherapy

IMRT, two step method (NOT SIB), 70 Gy/35 fx/7w

Initial plan, PTV1 46 Gy/23 fx

Boost plan, PTV2 24 Gy/12 fx

(on a separate CT set acquired after start of treatment)

Chemotherapy

Concurrent phase:

CDDP 80 mg/m2, div, day1 q3w, 3 cycles

Adjuvant phase:

CDDP 70 mg/m2, div, day1

5-FU 700 mg/m2, civ, day1-5 q3w, 3 cycles

Target accrual: approx. 70 pts in 4 yrs, follow up 3 yrs

Participating institutions: 10 or less

QA items to be collected for submission to ITC:

1) Initial review (NOT rapid review)

Initial plan (~46 Gy), planned as if 70 Gy prescription

CT, structure, dose, DVH (if DICOM-RT export is possible)

(Screen shots of DVH, diagnostic MRI/PET CT will be collected and reviewed but independent of ITC submission)

2) Final review

Boost plan (24 Gy), planned as if 70 Gy prescription

CT, structure, dose, DVH (if DICOM-RT export is possible)

(Screen shots of DVH, diagnostic MRI/PET CT will be collected and reviewed but independent of ITC submission)

Combining initial and boost plans is NOT expected/intended because these will be planned on different CT sets, and actual DVH cannot be analysed due to changes of structures.