ELIGIBILITY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 1
Version 2 april 2007

Initials					Date of Birth (dd/mm/yyyy)										
Hospital					Hospital record number										
Sequence number															

INCLUSION CRITERIA			
The inclusion criteria must all be marked **YES** for the patient to be eligible for the study		YES	NO
1.	Squamous cell cancer (scc) of the vulva with locally advanced disease not curable with surgery unless extensive reconstructive surgery or a colostomy or urostomy is performed		
2.	Treated with curative intent		
3.	No disease present outside the pelvis		
4.	WHO performance status 0-2		
5.	Measurable disease at least locally (vulvar area)		
6.	Patients must be fit enough to undergo salvage surgery after chemo radiotherapy		
7.	Pretreatment laboratory values - Hb > 6.5 mmol/l - Neutrophil count > 1.5 x 10^9/l - Platelets ≥ 100 x 10^9/l - Bilirubin < 25µmol/l - Adequate liver function: ALAT and ASAT < 2,5 x upper normal limit - Alkaline phosphatase < 2,5 x upper normal limit		
8.	Age > 18 years, no upper age limit specified. Patients should mentally, physically and geographically be able to undergo treatment and follow-up		
9.	Written informed consent, date signed ___/___/20___		
10.	No psychosis, CNS disease or other expected difficulty for follow-up		
11.	No active uncontrolled infection		
12.	No concomitant or previous malignancy other than basal cell carcinoma of the skin or CIN of the cervix		

REGISTRATION DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
D D M M Y Y Y Y

SEQUENTIAL STUDY NUMBER: ⌊_⌋⌊_⌋⌊_⌋

REGISTERED BY : ……

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
D D M M Y Y Y Y

ON STUDY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 2
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9			
Hospital				Hospital record number									
Sequence number													

INFORMED CONSENT

DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

PATIENT'S CHARACTERISTICS

WHO PERFORMANCE STATUS (0-2) ☐

T STAGE (1=T1, 2=T2, 3=T4, 4=T4) ☐

N STAGE (0=N0, 1=N1, 2=N2) ☐

WEIGHT ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

HEIGHT ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ cm

LABORATORY DATA

	OBSERVED VALUE	LOWER NORMAL LIMIT	UPPER NORMAL LIMIT
DATE SAMPLE TAKEN	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
LEUCOCYTES	⌊_⌋⌊_⌋ . ⌊_⌋ 10^9/L	⌊_⌋⌊_⌋ . ⌊_⌋ 10^9/L	⌊_⌋⌊_⌋ . ⌊_⌋ 10^9/L
PLATELETS	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ 10^9/L	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ 10^9/L	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ 10^9/L
HB	⌊_⌋⌊_⌋ . ⌊_⌋ mmol/l	⌊_⌋⌊_⌋ . ⌊_⌋ mmol/l	⌊_⌋⌊_⌋ . ⌊_⌋ mmol/l
SERUM CREATININE	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ µmol/l	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ µmol/l	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ µmol/l
ASAT/SGOT	⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋ U/l
ALAT/SGPT	⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋ U/l
BILIRUBIN	⌊_⌋⌊_⌋ . ⌊_⌋ µmol/l	⌊_⌋⌊_⌋ . ⌊_⌋ µmol/l	⌊_⌋⌊_⌋ . ⌊_⌋ µmol/l
ALKALINE PHOSPHATASE	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ U/l	⌊_⌋⌊_⌋⌊_⌋⌊_⌋ U/l

CONCURRENT DISEASES

CARDIOVASCULAR (1=NO; 2=YES, SPECIFY……..…..) ☐

ENDOCRINE (1=NO; 2=YES, SPECIFY……) ☐

OTHER (1=NO; 2=YES, SPECIFY……) ☐

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

D D M M Y Y Y Y

ON STUDY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 2
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9			
Hospital				Hospital record number									
Sequence number													

PRIMARY TUMOR CHARACTERISTICS

SQUAMOUS CELL CARCINOMA (PLEASE ENTER NUMBER IN BOX) — 1 = PRIMARY, 2 = RECURRENCE [ ]

TUMOUR (PLEASE ENTER NUMBER IN BOX) — 1 = UNIFOCAL, 2 = MULTIFOCAL [ ]

LOCALISATION (PLEASE ENTER NUMBER IN BOX) — 1 = LATERALIZED, 2 = MIDLINE [ ]

PATHOLOGY REVIEW (PLEASE ENTER NUMBER IN BOX) — 1 = NO, 2 = YES , PLEASE ENCLOSE COPY OF REPORT [ ]

DESCRIPTION OF THE PRIMARY TUMOUR AND LYMPH NODES

Please use the figure (see next page). Mention the clinical diameter of the tumour and the distances in mm to urethra, clitoris, anus, and midline. Indicate any palpable lymph nodes and any suspicious for malignancy.

MAXIMUM TUMOUR DIAMETER (CLINICAL)

_____X _____mm

MINIMUM DISTANCE IN MM TO:

- URETHRA _____mm or >10mm
- CLITORIS _____mm or >10mm
- ANUS _____mm or >10mm
- MIDLINE _____mm or >10mm

LYMPH NODES PALPABLE ? (PLEASE CIRCLE)

- LEFT NO YES
- RIGHT NO YES

LYMPH NODES SUSPICIOUS? (PLEASE CIRCLE)

- LEFT NO YES
- RIGHT NO YES

LYMPH NODES FIXED ? (PLEASE CIRCLE)

- LEFT NO YES
- RIGHT NO YES

LYMPHANGITIS ? (PLEASE CIRCLE)

- LEFT NO YES
- RIGHT NO YES

Investigator's signature:

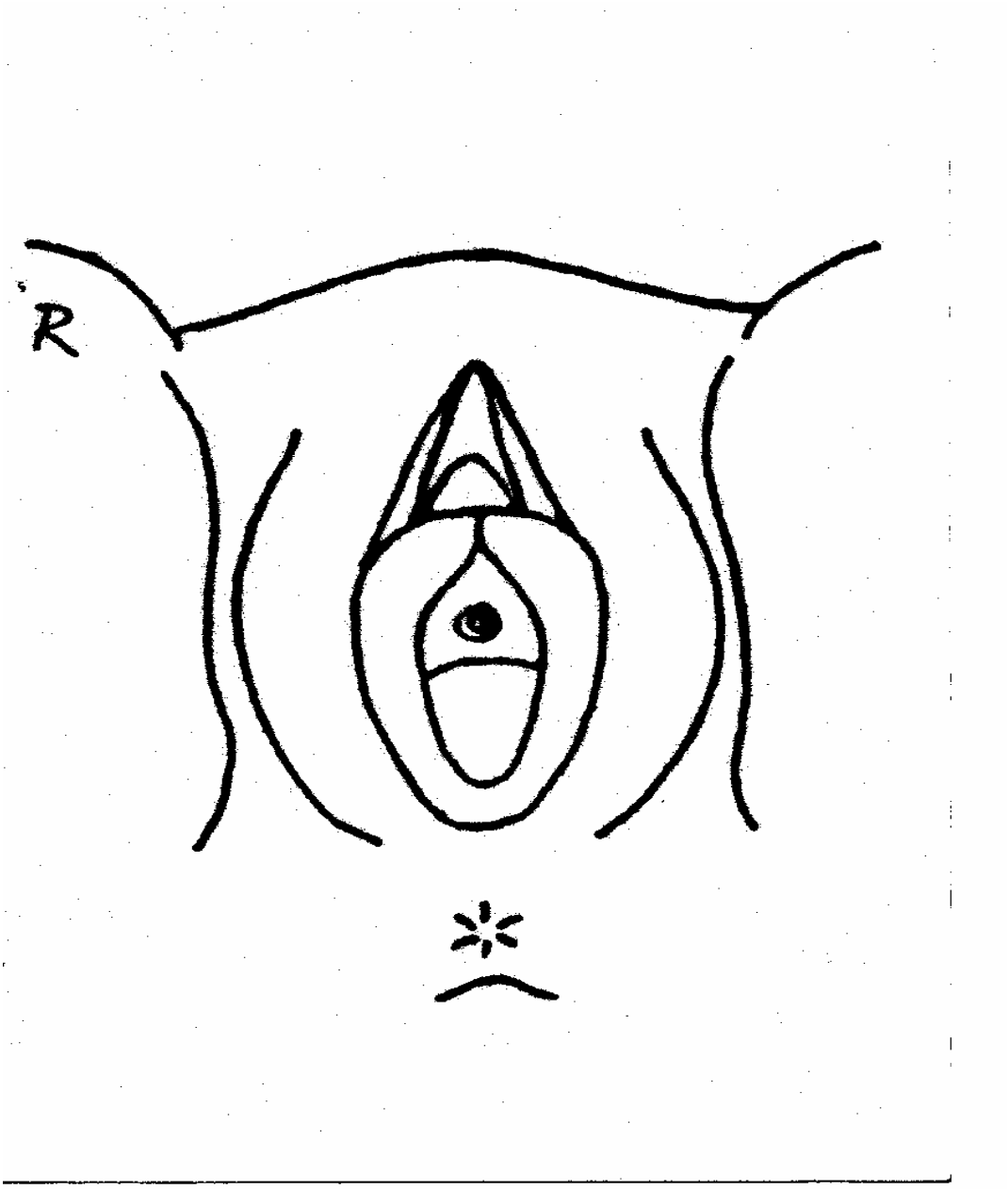
……..

Date:

D D M M Y Y Y Y

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

Figure 1
Please indicate in the figure the primary tumor, and/or any palpable or suspicious lymph nodes nodes. Add a digital photograph + visible ruler.



Investigator's signature:

……..

Date:

D D M M Y Y Y Y

ON STUDY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 2
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9			
Hospital				Hospital record number									
Sequence number													

BASELINE TOXICITY *(Instruction: Please complete prior to chemotherapy)*

TOXICITY (CTCAE version 3, grade 0-5, http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx)

NAUSEA
0 = none
1 = loss of appetite, no change eating habits
2 = oral intake decreased, no sign. weight loss, dehydration/malnutrition
3 = inadequate oral caloric intake or fluid intake, IV fluids, tube feeding or TPN
4= life-threatening consequences
5 = death

VOMITING
0 = none
1 = 1 episode in 24 hrs
2 = 2-5 episodes in 24 hrs, IV fluids indicated < 24 hrs
3 => 6 episodes in 24 hrs: IV fluids or TPN > 24hr
4= life-threatening consequences
5 = death

MUCOSITIS (upper digestive tract)
0 = none
1 = minimal symptoms, normal diet
2 = symptomatic but can eat and swallow modified diet
3 = symptomatic and unable to adequately aliment of hydrate orally
4= life-threatening consequences
5 = death

MUCOSITIS (lower digestive tract)
0 = none
1 = minimal discomfort
2 = symptomatic, medical intervention indicated
3 = stool incontinence or other symptoms interfering with daily activities
4 = life-threatening consequences
5 = death

DIARRHEA
0 = none
1 = increase of <4 stools over baseline, mild increase ostomy
2 = increase of 4-6 stools, IV fluids indicated, moderate increase ostomy
3 = increase of > 7 stools/day incontinence, IV fluids > 24 h, severe increase ostomy
4 = life-threatening consequences
5 = death

SKIN (rash / hand foot syndrome)
0 = none
1 = minimal skin changes or dermatitis, no pain
2 = scattered erythema, skin changes (peeling blisters) or pain
3 = severe generalized rash, skin changes with pain interfering with function
4 = life threating/disabling
5 = death

EDEMA (limb)
0 = none
1 = 5-10% inter-limb discrepancy in volume or circumference, pitting edema
2 = >10-30% inter-limb discrepancy, apparent obscuration of anatomic architecture, obliteration of skin folds
3 = >30% inter-limb discrepancy, lymphorrhea, deviation from normal anatomy
4 = amputation indicated: disabling
5 = death

SKIN (dermatitis)
0 = none
1 = slight erythema / dry desquamation
2 = moderate erythema / moist desquamation confines to skin folds
3 = confluent desquamation not confined to skin folds
4 = skin necrosis or ulceration full of thickness dermis
5 = death

G.I. ENTERITIS
0 = none
1 = asymptomatic, pathologic or radiologic findings only
2 = abdominal pain, mucus or blood in stool
3 = abdominal pain, fever, change in bowel habits with ileus
4 = life threatening consequences (perforation, bleeding, necrosis)
5 = death

G.I. ANAL INCONTINENCE
0 = none
1 = occasional use of pads required
2 = daily use of pads required
3 = interfering with daily activities, intervention indicated
4 = permanent bowel diversion indicated
5 = death

URINARY INCONTINENCE
0 = none
1 = occasional (coughing, sneezing)
2 = spontaneous, pads indicated
3 = interfering with daily activities, intervention indicated
4 = operative intervention indicated

PAIN
0 = none
1 = mild pain not interfering with function
2 = moderate pain, pain or analgesics interfering with function, but not with daily activities
3 = severe pain, pain or analgesics interfering with daily activities
4 = disabling

OTHER, specify……..

OTHER, specify……..

Investigator's signature:

……..

Date:

D D M M Y Y Y Y

TREATMENT FORM RADIOTHERAPY

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 3
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)						1	9		
Hospital				Hospital record number									
Sequence number				Center for radiotherapy									

RADIOTHERAPY

FIRST DAY OF RADIOTHERAPY DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

LAST DAY OF RADIOTHERAPY DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

TOTAL DOSE OF RADIOTHERAPY (GROINS) ____ Gy

TOTAL DOSE OF RADIOTHERAPY (VULVA) ____ Gy

REDUCTION OF RADIOTHERAPY DOSE # ____

# 0 = no	5 = other toxicity
1 = hematological toxicity	6 = not drug related
2 = gastrointestinal toxicity	8 = logistic
3 = dermatological toxicity	9 = unknown

INTERRUPTION OF RADIOTHERAPY # ____

RADIOTHERAPY STOPPED DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

RADIOTHERAPY RESUMED DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

PTV_{pt} (primary tumor)		**PTV_{LD}** (Lymphatic drainage)		**PTV_{LN}** (Lymph node)	
D100	____ Gy	D100	____ Gy	D100	____ Gy
D95	____ Gy	D95	____ Gy	D95	____ Gy
D90	____ Gy	D90	____ Gy	D90	____ Gy
V100	____ ml	V100	____ ml	V100	____ ml
V95	____ ml	V95	____ ml	V95	____ ml
V90	____ ml	V90	____ ml	V90	____ ml

Nagevraagd bij Baukelien hvh hokjes

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

D D M M Y Y Y Y

TREATMENT FORM CHEMOTHERAPY

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 4
Version 6 april 2007

Initials				Date of Birth (dd/mm/yyyy)						1	9		
Hospital				Hospital record number									
Sequence number				Center for chemotherapy									

CHEMOTHERAPY
PATIENTS CHARACTERISTICS

LENGTH ⌊_⌊_⌊_⌋ cm

WEIGHT ⌊_⌊_⌊_⌋ . ⌊_⌋ kg

BODY SURFACE AREA ⌊_⌋ . ⌊_⌊_⌋ m^2

DOSE AND DRUGS

TOTAL DAILY DOSE CAPECITABINE (BID) ⌊_⌊_⌊_⌊_⌋ mg

TOTAL DOSE CAPECITABINE GIVEN DURING CHEMORADIATION ⌊_⌊_⌊_⌊_⌊_⌊_⌋ mg

DATE START OF WEEK 1 (DAY 1) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
LAST TREATMENT WEEK 2 (DAY 14) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
DATE START OF WEEK 4 (DAY 22) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
LAST TREATMENT WEEK 5 (DAY 35) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
DATE START OF WEEK 7 (DAY 43) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
LAST TREATMENT WEEK 7 (DAY 49) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋

DOSE REDUCTION #

# 0 = no	4 = other toxicity
1 = hematological toxicity	5 = not drug related
2 = gastrointestinal toxicity	6 = logistic
3 = dermatological toxicity	9 = unknown

☐

AND SPECIFY INTERVAL:

REDUCTION STARTED (…% GIVEN) ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋

REDUCTION STOPPED ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋

DELAY # ☐
SPECIFY DELAY ……

TRANSFUSIONS (1=NO; 2=YES) ☐

Investigator's signature:

……..

Date: ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
D D M M Y Y Y Y

LABORATORY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 5
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)							1	9			
Hospital				Hospital record number											
Sequence number															

INSTRUCTION: *Please complete this form before chemoradiotherapy and every week during chemoradiotherapy and one week after chemoradiotherapy*

LAB:

DATE SAMPLE	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋
LEUCOCYTES	⌊⌊⌋.⌊⌊⌋ 10^9/L	⌊⌊⌋.⌊⌊⌋ 10^9/L	⌊⌊⌋.⌊⌊⌋ 10^9/L
PLATELETS	⌊⌊⌊⌋ 10^9/L	⌊⌊⌊⌋ 10^9/L	⌊⌊⌊⌋ 10^9/L
HB	⌊⌊⌋.⌊⌋ mmol/l	⌊⌊⌋.⌊⌋ mmol/l	⌊⌊⌋.⌊⌋ mmol/l
SERUM CREATININE	⌊⌊⌊⌋ µmol/l	⌊⌊⌊⌋ µmol/l	⌊⌊⌊⌋ µmol/l
ASAT/SGOT	⌊⌊⌋ U/l	⌊⌊⌋ U/l	⌊⌊⌋ U/l
ALAT/SGPT	⌊⌊⌋ U/l	⌊⌊⌋ U/l	⌊⌊⌋ U/l
BILIRUBIN	⌊⌊⌋.⌊⌋ µmol/l	⌊⌊⌋.⌊⌋ µmol/l	⌊⌊⌋.⌊⌋ µmol/l
ALK. PHOSPH.	⌊⌊⌊⌋ U/l	⌊⌊⌊⌋ U/l	⌊⌊⌊⌋ U/l

LAB:	**DAY** ⌊⌊⌋	**DAY** ⌊⌊⌋	**DAY** ⌊⌊⌋
DATE SAMPLE	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋	⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋
LEUCOCYTES	⌊⌊⌋.⌊⌊⌋ 10^9/L	⌊⌊⌋.⌊⌊⌋ 10^9/L	⌊⌊⌋.⌊⌊⌋ 10^9/L
PLATELETS	⌊⌊⌊⌋ 10^9/L	⌊⌊⌊⌋ 10^9/L	⌊⌊⌊⌋ 10^9/L
HB	⌊⌊⌋.⌊⌋ mmol/l	⌊⌊⌋.⌊⌋ mmol/l	⌊⌊⌋.⌊⌋ mmol/l
SERUM CREATININE	⌊⌊⌊⌋ µmol/l	⌊⌊⌊⌋ µmol/l	⌊⌊⌊⌋ µmol/l
ASAT/SGOT	⌊⌊⌋ U/l	⌊⌊⌋ U/l	⌊⌊⌋ U/l
ALAT/SGPT	⌊⌊⌋ U/l	⌊⌊⌋ U/l	⌊⌊⌋ U/l
BILIRUBIN	⌊⌊⌋.⌊⌋ µmol/l	⌊⌊⌋.⌊⌋ µmol/l	⌊⌊⌋.⌊⌋ µmol/l
ALK. PHOSPH.	⌊⌊⌊⌋ U/l	⌊⌊⌊⌋ U/l	⌊⌊⌊⌋ U/l

Investigator's signature:

……..

Date:

⌊⌊⌋⌊⌊⌋⌊⌊⌊⌊⌋
D D M M Y Y Y Y

TOXICITY FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 6
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

INSTRUCTION: *Fill in weekly during chemoradiation*
Toxicity ***CTCAE version 3, grade 0-5,*** *to be completed after each week of chemoradiotherapy* ***http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx***

DATE OF ASSESSMENT ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ **WEEK** ⌊_⌋

TOXICITY CHEMORADIOTHERAPY

NAUSEA
0 = none
1 = loss of appetite, no change eating habits
2 = oral intake decreased, no sign. weight loss, dehydration/malnutrition
3 = inadequate oral caloric intake or fluid intake, IV fluids, tube feeding or TPN
4= life-threatening consequences
5 = death

VOMITING
0 = none
1 = 1 episode in 24 hrs
2 = 2-5 episodes in 24 hrs, IV fluids indicated < 24 hrs
3 => 6 episodes in 24 hrs: IV fluids or TPN > 24hr
4= life-threatening consequences
5 = death

MUCOSITIS (upper digestive tract)
0 = none
1 = minimal symptoms, normal diet
2 = symptomatic but can eat and swallow modified diet
3 = symptomatic and unable to adequately aliment of hydrate orally
4= life-threatening consequences
5 = death

MUCOSITIS (lower digestive tract)
0 = none
1 = minimal discomfort
2 = symptomatic, medical intervention indicated
3 = stool incontinence or other symptoms interfering with daily activities
4 = life-threatening consequences
5 = death

DIARRHEA
0 = none
1 = increase of <4 stools over baseline, mild increase ostomy
2 = increase of 4-6 stools, IV fluids indicated, moderate increase ostomy
3 = increase of > 7 stools/day incontinence, IV fluids > 24 h, severe increase ostomy
4 = life-threatening consequences
5 = death

SKIN (rash / hand foot syndrome)
0 = none
1 = minimal skin changes or dermatitis, no pain
2 = scattered erythema, skin changes (peeling blisters) or pain
3 = severe generalized rash, skin changes with pain interfering with function
4 = life threating/disabling
5 = death

EDEMA (limb)
0 = none
1 = 5-10% inter-limb discrepancy in volume or circumference, pitting edema
2 = >10-30% inter-limb discrepancy, apparent obscuration of anatomic architecture, obliteration of skin folds
3 = >30% inter-limb discrepancy, lymphorrhea, deviation from normal anatomy
4 = amputation indicated: disabling
5 = death

SKIN (dermatitis)
0 = none
1 = slight erythema / dry desquamation
2 = moderate erythema / moist desquamation confines to skin folds
3 = confluent desquamation not confined to skin folds
4 = skin necrosis or ulceration full of thickness dermis
5 = death

G.I. ENTERITIS
0 = none
1 = asymptomatic, pathologic or radiologic findings only
2 = abdominal pain, mucus or blood in stool
3 = abdominal pain, fever, change in bowel habits with ileus
4 = life threatening consequences (perforation, bleeding, necrosis)
5 = death

G.I. ANAL INCONTINENCE
0 = none
1 = occasional use of pads required
2 = daily use of pads required
3 = interfering with daily activities, intervention indicated
4 = permanent bowel diversion indicated
5 = death

URINARY INCONTINENCE
0 = none
1 = occasional (coughing, sneezing)
2 = spontaneous, pads indicated
3 = interfering with daily activities, intervention indicated
4 = operative intervention indicated

PAIN
0 = none
1 = mild pain not interfering with function
2 = moderate pain, pain or analgesics interfering with function, but not with daily activities
3 = severe pain, pain or analgesics interfering with daily activities
4 = disabling

OTHER, specify……..

OTHER, specify……..

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
D D M M Y Y Y Y

EVALUATION FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 7
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

TREATMENT SUMMARY

RADIOTHERAPY COMPLETED ACCORDING PROTOCOL? (*) ☐

CHEMOTHERAPY COMPLETED ACCORDING PROTOCOL? (*) ☐

*) **Reason for treatment discontinuation:**
0 = Yes, completed according to protocol
1 = No, due to progression of the disease/relapse, including death due to malignant disease
2 = No, due to toxicity
3 = No, due to patient refusal
4 = No, due to intercurrent death (not due to malignant disease or toxicity)
5 = No, lost to follow-up
6= No, other, specify.....
9 = Unknown

LOCAL RESPONSE 12 WEEKS AFTER CHEMORADIOTHERAPY:

DATE OF ASSESSMENT ☐☐ ☐☐ ☐☐☐☐

1.= CR
2.= PR : > 30% DECREASE IN LARGEST DIAMETER
3.= PROGRESSIVE DISEASE: > 20% INCREASE IN LARGEST DIAMETER
4. = SD, STABLE DISEASE, BETWEEN 2 AND 3
8 = NOT EVALUBLE
9 = UNKNOWN

☐

(Please, add photo of local situation + ruler + diagram)

SURGERY INDICATED BASED ON LOCAL RESPONSE? (1= NO, 2= YES) ☐

REGIONAL RESPONSE 12 WEEKS AFTER CHEMORADIOTHERAPY

1.= CR
2.= PR : > 30% DECREASE IN LARGEST DIAMETER
3.= PROGRESSIVE DISEASE: > 20% INCREASE IN LARGEST DIAMETER
4. = SD, STABLE DISEASE, BETWEEN 2 AND 3
5 = NOT APPLICABLE
8 = NOT EVALUABLE
9 = UNKNOWN

☐

SURGERY INDICATED BASED ON REGIONAL RESPONSE? (1= NO, 2= YES) ☐

Investigator's signature:

……..

Date:

☐☐ ☐☐ ☐☐☐☐
D D M M Y Y Y Y

TREATMENT FORM SURGERY

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 8
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)						1	9		
Hospital				Hospital record number									
Sequence number													

INSTRUCTION: Use this form both for initial and secondary surgery

OPERATION:

DATE OF SURGERY ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋

OPERATIVE TIME (DURATION IN MINUTES): [ ]

SURGEONS:.....

.....

TYPE OF **LOCAL** OPERATION: [ ]
1=WIDE LOCAL EXCISION
2=RADICAL VULVECTOMIE
3=NO OPERATION

LOCAL RESPONSE [ ]
1.= CR
2.= PR : > 30% DECREASE IN LARGEST DIAMETER
3.= PROGRESSIVE DISEASE: > 20% INCREASE IN LARGEST DIAMETER
4. = SD, STABLE DISEASE, BETWEEN 2 AND 3
5. = NOT APPLICABLE, INITIAL SURGERY

(Please, add photo of local situation)

TYPE OF **REGIONAL** OPERATION**:** [ ]
1 = UNILATERAL LYMPHADENECTOMY VIA SEPARATE INCISIONS
2 = UNILATERAL LYMPHADENECTOMY EN BLOC
3 = BILATERAL LYMPHADENECTOMY VIA SEPARATE INCISIONS
4 = BILATERAL LYMPHADENECTOMY EN BLOC
5 = UNILATERAL LYMPH NODE DEBULKING
6 = BILATERAL LYMPH NODE DEBULKING
7 = NO OPERATION

REMOVAL OF**:**

CLITORIS	(1= NO, 2= YES)	[ ]
URETHRA > 1cm	(1= NO, 2= YES)	[ ]
ANUS	(1= NO, 2= YES)	[ ]

Investigator's signature:

……..

Date:

⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋
D D M M Y Y Y Y

TREATMENT FORM SURGERY

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 8
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

INSTRUCTION: Use this form both for initial and secondary surgery

OPERATION

RECONSTRUCTIVE SURGERY (1= NO, 2= YES*) ☐

*)IF YES: 1 = SKIN/SUBCUTANEOUS PEDICLEFLAP, UNILATERAL
2 = SKIN/SUBCUTANEOUS PEDICLEFLAP, BILATERAL
3 = MUSCULACUTANEOUS PEDICLEFLAP, UNILATERAL
4 = MUSCULACUTANEOUS PEDICLEFLAP , BILATERAL
5 = OTHER ☐

BLOODLOSS DURING SURGERY > 500 ML (1= NO, 2= YES) ☐

UROSTOMA (1= NO, 2= YES) ☐

COLOSTOMA (1= NO, 2= YES) ☐

LYMPHEDEMA (1= NO, 2= YES) ☐

OTHER MORBIDITY INVOLVING LEGS (1= NO, 2= YES*) ☐

*)IF YES, SPECIFY: ……..

ANTIBIOTICS (1= NO, 2= YES*) ☐

Investigator's signature:

……..

Date:

D D M M Y Y Y Y

POST OPERATIVE FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 9
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

INSTRUCTION: Use this form both for initial and secondary surgery

POSTOPERATIVE PERIOD

PERIOD OF ADMISSION

DATE OF SURGERY ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

DATE OF DISCHARGE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

COMPLICATIONS

WOUNDBREAKDOWN LEFT SIDE (1 = NO, 2 =YES, 3= N.A.) ☐

WOUNDBREAKDOWN RIGHT SIDE (1 = NO, 2 = YES, 3= N.A) ☐

COMPLICATIONS LOCAL SITE (1 = NO, 2 =YES, 3= N.A) ☐

URINARY TRACT INFECTION (1 = NO, 2 =YES) ☐

CELLULITIS (WITH ANTIBIOTICS) (1 = NO, 2 =YES) ☐

ADVISE TO WEAR STOCKINGS (1 = NO, 2 = YES) ☐

MAJOR COMPLICATIONS*):……

……

……

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

D D M M Y Y Y Y

PATHOLOGY REPORT FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 10
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

PATHOLOGY REPORT

DATE ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

NUMBER T

LOCAL: 1 = NO RESIDUAL TUMOR
2 = RESIDUAL TUMOR

IN CASE OF RESIDUAL TUMOR:

DIAMETER mm

DEPTH OF INVASION mm

1 = UNIFOCAL OR 2 = MULTIFOCAL

TUMOR FREE RESECTION EDGE mm

GROINS:

NUMBER OF REMOVED LYMPH NODES LEFT

NUMBER OF LYMPHNODE METASTASES LEFT

NUMBER OF REMOVED LYMPH NODES RIGHT

NUMBER OF LYMPHNODE METASTASES RIGHT

Investigator's signature:

……..

Date:

⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

D D M M Y Y Y Y

FOLLOW UP FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 11
Version 2 april 2007

Initials				Date of Birth (dd/mm/yyyy)					1	9		
Hospital				Hospital record number								
Sequence number												

FOLLOW UP

SEQUENCENUMBER OF FOLLOW UP VISIT ☐

IS THIS PATIENT STILL ALIVE? ☐
(1 = NO; 2 =YES, 3 = LOST TO FOLLOW UP)

DATE OF VISIT/DEATH ☐☐ ☐☐ ☐☐☐☐

PERFORMANCE STATUS (ECOG 0-4) ☐

DISEASE STATUS
(1=NO EVIDENCE OF DISEASE, 2 = RECURRENCE)

VULVA ☐

LEFT GROIN ☐

RIGHT GROIN ☐

OTHER,…….. ☐

LATE MORBIDITY (1= NO; 2 = YES)

LYMPHEDEMA LEFT LEG	☐	PAINFUL LEG(S)	☐
LYMPHEDEMA RIGHT LEG	☐	URINARY INCONTINENCE	☐
RECURRENT ERYSIPELAS	☐	FECAL INCONTINENCE	☐
LATE RADIATION SKIN TOXICITY	☐	OTHER, specify…….	☐

Investigator's signature:

……..

Date:

☐☐ ☐☐ ☐☐☐☐
D D M M Y Y Y Y

SERIOUS ADVERSE EVENTS FORM

PHASE II STUDY OF DEFINITIVE CHEMORADIOTHERAPY FOR LOCAL ADVANCED SQUAMOUS CELL CANCER OF THE VULVA: AN EFFICACY STUDY

Form 13

PAGE 1 OF 1 ***This form should be faxed within 24 hrs of occurrence of the SAE to IKA trialbureau- 020-3462525***

Version 18 july 2006

HOSPITAL:	PATIENT LOCAL STUDY NUMBER::
	PATIENT INITIALS:
REPORT DATE: ……../……../…….. DD MM YYYY FOLLOW UP: ……../……../…….. DD MM YYYY FINAL: ……../……../…….. DD MM YYYY	CATEGORY OF EVENT 1= DEATH 2= LIFE TREATENING 3= HOSPITALISATION/PROLONGATION OF 4= PERSISTANT OR SIGNIFICANT DISABLILITY/INCAPACITY 5= CONGENITAL ANOMALY/BIRTH DEFECT

PLEASE, BRIEFLY DESCRIBE THE SERIOUS ADVERSE EVENT/SERIOUS ADVERS DRUG REACTION AND TREATMENT GEVEN. INCLUDE ANY RELEVANT MEDICAL HISTORY.

ONSET DATE: ……../……../…….. DD MM YYYY RESOLUTION DATE ……../……../…….. DD MM YYYY	SEVERITY 1= GRADE I/MILD 2= GRADE II/MODERATE 3= GRADE III/SEVERE 4= GRADE IV/LIFE THREATENING 5= GRADE V/FATAL ☐	RELATIONSHIP TO TREATMENT 0= UNRELATED 1= UNLIKELY 2= POSSIBLE 3= PROBABLE 4= DEFINITE 5= NOT ASSESSABLE ☐	ACTION TAKEN 0= NONE 1= DOSE REDUCED 2= TREATMENT DELAYED 3= TREATMENT REDUCED AND DELAYED 4= WITHDRAWN FROM STUDY ☐
TREATMENT REQUIRED 0= NONE 1= SYMPTOMATIC 2= SUPPORTIVE 3= VIGOROUS SUPPORTIVE ☐	OUTCOME 1= RESOLVED 2= RESOLVED WITH SEQUELA 3= IMPROVED 4= UNCHANGED 5= WORSENED 6= ONGOING WIH SEQUELA 7= UNKNOWN ☐		
DATE: ……../……../…….. DD MM YYYY		SIGNATURE OF REPORTER: ……	

Investigator's signature:

……..

Date:

D D M M Y Y Y Y