TATA MEMORIAL CENTRE
CLINICAL TRIALS/RESEARCH PROJECTS
SANCTION FORM

Project Title
CONCOMITTANT CHEMO-RADIATION IN ADVANCE STAGE CARCINOMA CERVIX - A PHASE - III RANDOMIZED TRIAL

Principal Investigator
SK SHRIVASTAVA *

Co-Principal Investigators
KA DINSHAW *, HB TONGAONKAR**, P PARIKH***,

Co-investigators
V SHARMA*, RA KERKAR**, S GUPTA***,
S GHOSH*, MAHISHWARI**, U MAHANTSHETTY*

Departments
Department of *Radiation Oncology, **Surgical Oncology, ***Medical Oncology, Tata Memorial Hospital.

Sponsors
Grants
To be submitted for funding from ICMR Delhi.

SCIENTIFIC COMMITTEE
The Scientific Committee of the Tata Memorial Hospital has reviewed the above project and granted approval.
Date: ....................
Place: MUMBAI Secretary Chairman
Name: ......................... Name: .....................

ETHICS COMMITTEE
The Ethics Committee of the Tata Memorial Hospital has reviewed the above project and granted approval.

*Note: The PI of this study has stayed away from the evaluation process and voting approval for this study.

Date: .................... Secretary Chairman
Place: MUMBAI Name: ......................... Name: .....................
TATA MEMORIAL CENTRE
APPLICATION FOR RESEARCH PROJECTS SUBMITTED TO
ETHICS COMMITTEE.

1. This research proposal is routed to the Ethics Committee through the Scientific Committee and is accompanied by the approval and recommendations of that Committee.

2. The proposal is accompanied by full details on funding. We understand that the Ethics Committee is concerned that financial transactions meet with ethical principles.

3. The budget presentation is presented on the following sheet.

4. 5% of the total budget will be credited to the Hospital as service charges.

5. If the research proposal is undertaken on behalf of a pharmaceutical company, the company will underwrite all expenses such that neither the hospital nor the patients are made to spend. In the event of complications, the company will underwrite the cost of management of these.

6. We state that the research officers do /do not stand to gain materially from the project.

7. The salaries to staff employed for the research project as shown in the attached budget are as per TMC scales.

8. The data collected under any research project undertaken, including that carried out using funds from a commercial organization such as a pharmaceutical company, will remain the property of Tata Memorial Hospital and the records will be preserved on its premises. The analysis of such data and conclusions from it shall be made by the Research Officers and not by the sponsoring company.

9. The findings and conclusions of all studies carried out within this situation including review of patients, analysis of forms or treatment, analysis of investigative findings and research projects will be presented to the staff members of this institute before they are released or presented elsewhere. The submission will be made well in advance of any presentation at conferences or seminars elsewhere. We undertake to inform the Administration at Tata Memorial Center of all such presentation of this data, nationally and internationally.

Date: ..........................  Code No.: ..........................
10. No press release will be issued before the data and conclusions have been peer-reviewed with the hospital or published in an indexed journal.

11. The form we shall use to ensure informed consent is attached. It explains the main features of the trial and side effects if any.

12. Any mishap during the trial will be the responsibility of the Principal Investigator. Moreover if any adverse events occur, these will be reported to the Scientific and Ethics Committees.

**WE AGREE TO THE ABOVE:**

Date:

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Signatures:</th>
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<tbody>
<tr>
<td>Dr SK SHRIVASTAVA</td>
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</table>

<table>
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<tr>
<th>Co-Principal Investigators</th>
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<tbody>
<tr>
<td>Dr KA DINSHAW</td>
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<td>Dr HB TONGAONKAR</td>
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<td>Dr P. PARIKH</td>
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<tr>
<td>Dr V SHARMA</td>
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<td>Dr S GUPTA</td>
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<td>Dr S GHOSH</td>
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<tr>
<td>Dr A VORA [MAHESHWARI]</td>
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<tr>
<td>Dr U MAHANTSHETTY</td>
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BUDGET

I. Title of the Project: CONCOMITTANT CHEMO-RADIATION IN ADVANCED STAGE CARCINOMA CERVIX - A PHASE-III RANDOMIZED TRIAL

II. Name and Designation of

   I. Principal Investigator Dr. SK SHRIVASTAVA*

   II. Co-Principal Investigators Dr KA DINSHAW *

      Dr HB TONGAONKAR**

      Dr P PARIKH***

   III. Co-Investigators DR V SHARMA*,

         DR RA KERKAR**

         DR S GUPTA***, DR S GHOSH*  

         DR, A VORA**, DR U MAHANTSHETTY***

         *Department of Oncology,

         **Department of Oncology,

         ***Department of Oncology,

         Radiation, Surgical, Medical

III. Sponsoring Collaborating Institution (Address)

To be Applied for funding to ICMR Delhi.

Principal Collaborator (Individual’s name, designation and address)

Nil

IV. Duration of the Project

I) Period (No. of years) 5 years

II) Tentative starting date Jan 2003

III) Period for collecting data 5 years

IV) Period for complete analysis of data 6 months
V. SUMMARY BUDGET ESTIMATE (IN RUPEES)

<table>
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<tr>
<th>ITEMS</th>
<th>1st Year</th>
<th>2nd Year</th>
<th>3rd Year</th>
<th>4th Year</th>
<th>5th Year</th>
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<td>8. Any other benefits to investigators</td>
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VI. Any other benefits to investigators: Nil

P.S. Please use additional sheets if needed.
BRIEF QUESTIONNAIRE FOR PROJECTS PRESENTED FOR
ETHICAL APPROVAL

To be filled in by the Principal Investigators

Name: SK SHRIVASTAVA and KA DINSHAW
Address: Department of Radiation Oncology
          Tata Memorial Hospital
Start Date: Jan 2003
Sponsor/Funding Agency: To be applied for funding from ICMR Delhi
Conflict of Interest: Nil
Project Title: CONCOMITANT CHEMO-RADIATION IN ADVANCED
               STAGE CARCINOMA CERVIX - A PHASE-III
               RANDOMIZED TRIAL

1. Women with carcinoma cervix stage III referred for radiation will be randomized to
   receive either radiotherapy alone or concomitant chemo-radiation. The total
   radiation dose, fractionation and intra-cavitary radiation will remain same in both
   the treatment arms. Concomitant Cis-platin based chemotherapy has the potential
   to improve the survivals as compared to radiotherapy alone with acceptable toxicity
   that is being evaluated in this trial.

2. Women below the age of 65 years with carcinoma cervix fulfilling the eligibility
   criteria will be invited to participate in the trial after informed consent.

3. Patient population in the study for the arms will be recruited from the patients with
   cervical cancers referred to Tata Memorial Hospital for management.

4. Patients in the concomitant chemo-radiation arm may have an additional risk of
   non-significant hematological toxicity as compared to the radiation alone arm.

5. All records will be kept confidential and only the investigators will have access to
   them.

6. Patients in the radiation therapy alone arm will receive the standard treatment that
   is currently being used in our department and worldwide.

7. The procedures of concomitant chemotherapy needs an Intravenous line for
   Cisplatin and IV Fluids infusion weekly which is not a major procedure and is not
   associated with any life-threatening complications. These patients will be reviewed
   regularly by Radiation and Medical Oncologist and any problems will be managed
   accordingly.
8. Any added complications attributable directly to the treatment in both the arms will be managed by the investigators from the ICMR funding.

9. The procedure of radiation and chemo-radiation will be described in detail to the patients and their families. They will also be explained about the follow-up and investigations to be carried out regularly. We do not anticipate any emotional upsets in these patients. Our hospital Clinical Psychologist will address psychological problems, if any.

10. Every effort will be taken to explain the procedure and the relevant details of the trial to the patients in the language they understand. Additional help from interpreters will be taken for patients who do not understand Hindi, English or Marathi.

11. The trial records will be maintained in the Central Research Secretariat (CRS) of the Tata Memorial Centre.

12. With concomitant chemo-radiation therapy we anticipate improvement in the survivals which had attained a plateau with radiation therapy alone. Although we expect additional hematological toxicity in chemo-radiation arm which can be tackled with supportive and standard of care available at our Hospital today.

13. We have not made any specific provisions for insurance against legal action for the project.

Concomitant Chemo-radiation in Advanced Stage Carcinoma Cervix
A Phase III Randomized Trial

BACKGROUND AND RATIONALE:

Carcinoma cervix is the commonest malignancy seen in Asian women and constitutes approximately 30% of all cancers (1). It is also the leading cause of cancer mortality in India. Nearly 50% of the patients present with advanced stages (FIGO Stage III/IV). The mainstay of treatment has traditionally been radical radiation therapy and over decades the survival rates have achieved a plateau of 30 - 45% at 5 years. In developing countries the socioeconomic problems, illiteracy, late presentation and irregular follow-up have further compromised our survivals. Over the last decade there have been studies on the use of chemo-radiotherapy in carcinoma cervix. Over 19 randomized trials have been published addressing the issue of chemo-radiotherapy. However, heterogeneous data, poor randomization, inadequate number of patients, sub-optimal radiotherapy, non-uniform use of chemotherapeutic drugs, its sequencing and poor documentation have not yet provided the evidence to substantially alter the practice. Hence, meta-analysis of these trials was undertaken to further evaluate the role of chemo-radiotherapy in carcinoma cervix (2,3).

The first meta-analysis published by Cochrane Collaborative Group of 4580 randomized patients (19 randomized trials) suggested that chemo-radiation did show an absolute survival benefit improvement both in progression free and overall survivals by 16% and 12%
respectively (p<0.0001). The survivals were significantly better with Cisplatin based concomitant chemo-radiation (p<0.0001). Incidentally, the distant metastasis rates were also significantly lower in chemo-radiation (p<0.0001). However, all these benefits were seen only in early stages. In addition, acute grade 3/4 hematological and gastro-intestinal toxicities were higher with chemo-radiation (additional 8% and 5% respectively). The data was insufficient to report on late toxicity (2).

The second meta-analysis of 9 randomized trials, recently published by the Canadian Group to evaluate only cisplatin based concomitant chemo-radiation confirms the improvement in overall survival (4-year survival data) in advanced stages, bulky IB tumors (prior to surgery) and high risk early disease (post-surgery). Although acute grade 3/4 hematological and gastro-intestinal toxicities were higher in chemo-radiation, they were short-lived, with only 2 deaths and the remaining resolved with medical treatment. There was no significant increase in the late toxicity from the data available.

Both the Cochrane and Canadian meta-analysis have to a large extent tried to address the role of concomitant chemo-radiation, but Carcinoma Cervix Stage III accounted for only 30-35% and moreover evaluation with optimal radiation schedules and comparison of late toxicities still remains unanswered. What is more important is that the cisplatin is relatively inexpensive and is available worldwide. This means that cisplatin-based chemo-radiation is affordable in the developing countries where carcinoma cervix still forms the major cancer. However, the role of chemo-radiation in Carcinoma Cervix Stage III in a developing countries including India still remains unexplored. We propose this randomized study to evaluate the role and benefit of chemo-radiation in-patients with cervical cancer.

AIMS AND OBJECTIVES:

- PRIMARY:
  1. To evaluate the single agent concomitant chemotherapy (Cisplatin) in Stage IIIB carcinoma cervix
  2. To compare the disease free survivals.
  3. To compare the normal tissue toxicities (Acute & Late) of standard radiation therapy with concomitant chemo-radiation.

- SECONDARY:
  1. To compare the overall survivals
  2. To compare the distant metastasis rates
  3. To compare the quality of life in both the groups

PATIENT SELECTION:

Patients will be explained regarding the study objectives, possible added toxicities and potential benefits of the study arm. A written consent will be obtained from the patients before inclusion in the study.

Inclusion criteria:
- Histologically proven squamous carcinoma of cervix
• Performance index WHO grade 0 or 1
• Patients below 65 years of age
• FIGO Stage IIIB
• Normal ECG and Cardiovascular system
• Normal hematological parameters
• Normal renal and liver function tests

Exclusion criteria:
• Co-morbid conditions like medical renal disease
• Medical or Psychological condition that would preclude treatment
• H/o Previous treatment / Pregnancy
• Patient unreliable for treatment completion and follow-up.

PRETREATMENT EVALUATION:
• Complete Physical Examination including gynecological examination
• Complete blood profile including hemoglobin, total and differential counts, platelets
• Serum biochemistry - liver and renal function, electrolytes
• Blood grouping and HIV
• Urine Routine
• Chest X-ray
• Ultrasonography of Abdomen and Pelvis
• ECG (GA Fitness)
• Histopathological confirmation
• Cystoscopy if clinical suspicion off bladder infiltration
• IVP (if necessary)

STATISTICS: We propose to randomize the patients to either the Standard arm of Radical radiation therapy alone or the study arm-Concurrent chemo-radiation with Cisplatin weekly. Randomization will be done before the start of treatment by computer based randomization program and analysis will be carried out with an intent-to-treat basis. With an expected improvement in absolute survival by 10% for stages IIIB, α-error of 0.05, power of detection of 80% and 10% patients more to compensate for lost-to-follow-up and major violations, a total of 850 patients will be randomized with stratification for stages and brachytherapy treatment. Interim Analysis will be done twice one at 50% (230 events) event rates and another at 75% (350 events) event rates. The trial will be stopped if the difference in survival is significant with p< 0.001 and p<0.01 for 50% and 75% event rates respectively.

ACCRUAL DETAILS:
ACCRUAL PERIOD : 3 years
DURATION OF STUDY : 5 years
TENTATIVE STARTING DATE : January 2003
COMPLETE ANALYSIS : December 2008

TREATMENT PROTOCOL:

RADIATION THERAPY:
External Beam Radiation Therapy
All patients will be treated after simulation with either 6/10MV photons or 60Cobalt gamma rays to the pelvis. The target volume will include the pelvis from L5-S1 level superiorly to the obturator foramen inferiorly and laterally 1.5 to 2 cm beyond the pelvic brim. The total dose will
be defined at the mid-plane of the pelvis when treated with parallel opposing AP-PA portals and the point on cervix when treated with box field arrangements with a daily dose of 200cGy/# for 4-5 weeks. The patients will be reviewed weekly during the external radiotherapy and all the toxicities will be monitored with proper documentation. The total dose of external radiation will depend on the stage of the disease as mentioned in treatment design below.

Intracavitary Radiation Therapy (Brachytherapy)
Patients will be treated either with low dose or high dose brachytherapy. Patients for low dose rate brachytherapy will receive one low dose rate intracavitary, within 2 weeks after completion of external radiation. Patient will be admitted one day prior to the procedure. The procedure will be done under general anesthesia. The position of the applicators will be checked with orthogonal films. Bladder and rectum dose calculations will be done as per ICRU-38 recommendations. The dose of 30Gy will be delivered to point “A” with a dose rate of 145-165cGy/ hour.

Patients for high dose rate brachytherapy will receive 3 fractions of intracavitary brachytherapy. The first insertion will be will be either after completion of 30 Gy depending on the number of fractions required. Patient will be admitted for the first fraction after which she will receive intracavitary treatment as an outpatient subsequently every week. At each fraction patient will receive 7Gy to point “A”. The treatment will be delivered with high dose rate remote afterloading 192Ir|idium micro-Selectron machine.

Chemotherapy
Patients randomized for the chemotherapy will receive Inj. Cisplatin 40 mg/m² weekly once during the course of external radiation therapy, preferably on every Monday/Tuesday/Wednesday. All patients will be pre medicated with Onhardt (16 mg) and Dexametason (8 mg). Pre and Post Cisplatin hydration will also be given. Hematological evaluation (weekly) and renal function tests (biweekly) will be monitored in all patients.

EVALUATION OF RESPONSE AND TOXICITY:
Patients will be evaluated at regular interval for the tumor response and assessment of toxicities. The evaluation consists of complete physical check-up and whenever necessary appropriate laboratory tests. The assessment of the tumor response will be done according to WHO criteria of tumor response.

Response criteria (WHO):
CR (Complete response): Complete disappearance of all known disease for at least 4 weeks.
PR (Partial response): Established decrease in tumor size of 50% or more for at least 4 weeks.
NR (No response): No significant change for at least 4 weeks. This includes stable disease, estimated decrease of less than 50% and lesions with estimated increase if less than 25%.
PD (Progressive disease): Appearance of any new lesion not previously identified or estimated increase of 25% or more.

Toxicity Scoring:
The Acute Toxicity will be scored according to the CTC Version 2.0. Treatment will be delayed or interrupted for all the patients with Grade 3 toxicity and restarted after toxicity is < Grade 2. The late toxicity will be graded according to the LENT-SOMA Scoring Criteria.
FOLLOW-UP
Each patient will be followed-up every 3-4 months for first two years, every 6 monthly for 2 years and yearly thereafter. At each time complete clinical examination, assessment of late complication and relevant investigations will be done accordingly.

PROTOCOL VIOLATIONS:

MAJOR: All patients other than toxicity-related with one of the below criteria
1. <75% of total radiation treatment
2. No or single Brachytherapy treatment
3. Treatment interruptions/delay > 3 weeks
4. Chemotherapy <3 cycles

MINOR: 1. Alteration in Brachytherapy doses
2. Treatment interruptions/delay < 2 weeks
3. Chemotherapy: Delay/reduction by 1 cycle

TREATMENT DESIGN
Carcinoma Cervix Stage III B

Randomize

Group I
Radiotherapy Alone

Group II
Chemo-Radiation

Inj. Cisplatin 40 mg / M² weekly (every Mon/Tue/Wed) during Ext. RT

RT as below

External Radiation Therapy to Pelvis
50 Gy / 25 # / 5 Weeks
[40 Gy / 20 # / 4Wk (2-4 fields: open) + 10 Gy / 5 # / 1 Wk (AP/PA with MLB)]
INTRACAVITARY BRACHTHERAPY

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<thead>
<tr>
<th>LDR</th>
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<tbody>
<tr>
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<td>(7 Gy x 3#)</td>
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<td>to .A</td>
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<td>Wk 6</td>
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NB:  
* LDR rectal maximum dose should not be >60% of point A dose for each fraction  
* LDR bladder maximum dose should not be >70-80% of point A dose for each fraction  
* HDR rectal maximum dose should not be >60% of point A dose for each fraction  
* HDR bladder maximum dose should not be >70-80% of point A dose for each fraction  
* Consider parametrial /Pelvic side wall boost (180 cGy x 5) of the involved side.
CONCOMITANT CHEMO-RADIATION IN
ADVANCED STAGE CARCINOMA CERVIX-A PHASE-III RANDOMIZED TRIAL

PATIENT INFORMATION SHEET AND INFORMED CONSENT

You are being invited to participate in a study to evaluate the efficacy of concomitant chemoradiation as compared to radiotherapy alone. Concomitant chemoradiation is not a new treatment modality for carcinoma cervix. Studies have shown improvement in survivals with chemoradiation, but majority of the patients was in early stages. Since this treatment modality has not been tested adequately in advanced stages in our setting, the present study is being undertaken. The study arm of chemoradiation has the potential to improve the survivals by 10%, but is associated with additional 5% risk of toxicities, which are treatable.

In the study arm, apart from the standard radiotherapy treatment, you will receive weekly chemotherapy injections (Cisplatin) during external radiation therapy. The study arm is associated with additional 5% acute hematological and gastrointestinal toxicities, which are treatable with medications, blood transfusions, modifications in the ongoing treatment etc.

Your participation in this study is entirely voluntary and refusal/withdrawal to participate is your privilege. We emphasize that this will not compromise your treatment and care given by your doctor and the medical team. Please also note that you will not have to bear any additional expenses for treatment-related toxicity / investigations as a part of the study.

I understand that I am suffering from cervical cancer and been explained in detail about the disease, treatment options, side effects and the outcome. This study has been explained to me in my vernacular. I have fully understood the details of the study and hereby give my permission to participate in the study.

Patient’s Name: __________________________ Signature: __________________________

Name of witness: __________________________ Signature: __________________________

Investigator’s Signature: __________________________

Date: __________________________
तारीख € ........................................... कोड के € ......................................

सहगामी रसायन-विकिरण
गर्भाशयाच्या कर्करोगामधील सहगामी रसायनविकिरण भाग-३ अनिवर्त पद्धती

रुग्णासाठी माहिती आणि संगती पद

आम्ही तुम्हाला जोडूने घ्यावंयाच्या रसायन-विकिरण उपचार व फक्त विकिरण उपचार यांच्या तुलनात्मक अभ्यासात सहभागी होण्यासाठी आमंत्रित करत आहात. जोड रसायन-विकिरण उपचार पद्धती गर्भाशयाच्या कर्करोगामध्ये काही नवीन नाही. पुरातन अभ्यासानुसार असे सिद्ध होते आहे की हया उपचारातून रोगांचे आत्मघात वाढते जर कर्करोगाचा टप्पा लवकरचा असेल तर. वरील उपचार पद्धतीत हा पुरातत्त्वाचे जातात पारदर्शी व्यावसायिक कर्करोगामध्ये इम्पोर्टेंट असतील नाही. त्याच्या अन्यायांत जबाबदार राहीला आहे. हया उपचार पद्धतीतून १० तक्या रोगाचे जातात जोकमान जगातात पण व्यावसायात ५ तक्या वेळभर ठेवणे असे वापर करता येतात.

हया अभ्यासात् माहिती एक भाग हा योग्य असा विकिरण पद्धतीच्या बरोबरी आहे. इतरस्थानातून एकदा टोचून त्यांना माहिती सोडली गेली (मिसरप्लेटिंग इलेक्ट्रॉन) असेल. हया अभ्यासात्तिमाधील ५ तक्या रक्त व पॅटा संंदर्भातील त्रास होऊ शकते व तो उपचारात रुग्णाचे आपल्यांचे, रक्त वदल उपचार पद्धतीने वरा केला जाईल.

हया अभ्यासातील तुम्हाचा सहभाग हा पूर्णपणे एकत्रिक असेल तसेच हयाचा नकार / माहिती घेणे हयाचा अविकार आयुर्विज्ञानकडे राहील. आम्ही ज्ञानपणे सांगू शकतो की हयाचे अभ्यास उपचारात कोणतीही तड्डीडाळ करत नाही आणि आमचा बेदमकीय गटकरून पूर्णपणे काढून घेतली जाईल. तसेच हयासाठी ध्येयांमध्ये त्याच्या जांच व विश्लेषण हयाचा खार्च करावा लागणार नाही कारण हा एक अभ्यासाचा भाग आहे याची कृपया नोंद घ्यावे.

मला समजू आहे की भी गर्भाशयाच्या कर्करोगामधील आजार आहे आणि रोगांची माहिती उपचार पद्धती ह्यांना परिपरिणाम आणि हयाच्या बोधात आहे. हा अभ्यास मला माहिती मान्यमेर्त संगणित आला आहे. मला हया अभ्यासाचा संपूर्ण तपशील करायला आहे आणि स्वास्थ्यमें नाला सहभागी करून देण्याची अनुमती देत आहे.

रुग्णाचे नाव € .......................................................... स्वास्थ्य € ..........................
साहीजाराचे नाव .......................................................... स्वास्थ्य € ..........................
तपासनिसाठी सही € ..........................................
तारीख € ...........................................
दिनांक € ........................................... कोड के € ......................................
गर्भाशय मुख के केंद्र में समवाय औषधि एवं विकिरण चिकित्सा III अनिचारित परीक्षण

रोगीका जानकारी एवं संपत्ति पत्र

आपके रोग के लिये हम आपको औषधि एवं विकिरण चिकित्सा के समवाय प्रभाव के तुलनात्मक
अध्ययन के लिए आमंत्रित करते हैं। औषधि एवं विकिरण चिकित्सा की समवाय पद्धति कोई नयी
विधि नहीं है। अध्ययन द्वारा ज्ञात हुआ है कि इन दोनों विधाओं के समन्वय से इलाज का प्रतिफल रोग
के प्रारम्भिक अवस्था के केंद्र में अधिक उत्तम देखा गया है। परन्तु हमारी परिस्थितियों में इस पद्धति
का अध्ययन पर्याप्त रूप में नहीं किया गया है। अतः हमने यह अध्ययन करने का कार्यक्रम लिया है।
आशा है कि अध्ययन वर्ग में रोग के अच्छे होने की सामान्य 10% अधिक होगी, परन्तु साथ ही 5%
अधिक दुपुरियाम होने की संभावना है।

“नियंत्रक वर्ग” के रोगियों को मानक विकिरण चिकित्सा पद्धति की जायगी एवं “अध्ययन वर्ग” के
रोगियों को इसके साथ औषधि (सिम्बलिटिम इन्जेक्शन) भी दी जायगी। ‘अध्ययन वर्ग’ के रोगियों में
5% अधिक ‘रक्त एवं ऑंट’ समयन्त्र दुपुरियाम हो सकते हैं। इन सभी दुपुरियामों का इलाज
आसानी से किया जा सकता है।

आपका इस अध्ययन में शामिल होना पूर्णरूप से आपकी स्वतंत्रता से है। इसमें सम्मिलित होने के लिये
अपनीकार करना अथवा बाद में बाहर आने का अधिकार आपका है। महत्वपूर्ण बात यह है कि आपके
निर्णय से आपके इलाज में किसी भी प्रकार का समझौता नहीं किया जायेगा। इस अध्ययन कार्य में
शामिल होने से आपको किसी भी प्रकार का अतिरिक्त व्यय नहीं होगा।

इसे ज्ञात है कि मुझे गर्भाशय मुख का केंद्र नहीं है। मुझे इसके बारे में चिकित्सा पद्धति विकल्प दुपुरियाम
eव्यक्ति परियों द्वारा विश्वासित गया है। इस अध्ययन के विषय में मुझे मेरी वेश्याचरण भाव में
अवगत कराया गया है। में पूर्ण रूप से इस अध्ययन के विषय में समझ गयी हूँ एवं इसमें सम्मिलित होने
की अनुमति दी हूँ।

रोगी का नाम: ........................................................................................................ हस्ताक्षर: 
साक्षात्कार का नाम: .................................................................................................... हस्ताक्षर:
अध्ययन कार्य के हस्ताक्षर: ........................................................................................................
दिनांक: ........................................................................................................................

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