

## For trial participants

You are being invited to take part in a cancer research study. Before you decide to take part it is important you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

A summary of the principles of clinical trials can be found on the [Cancer Research UK's patient website \(http://www.cancerhelp.org.uk\)](http://www.cancerhelp.org.uk) together with information about this trial.

### Aims

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Although we know that chemotherapy with platinum containing anti-cancer drugs are the best treatment we still do not know which platinum drugs are the best or the amount of drug which produces the best results. This is important because higher doses of anti-cancer drugs have worse side effects than lower doses of the same drug.

However a higher dose may be worthwhile if it works better to prolong life and control symptoms than the lower dose. This study has been set up to discover which of the two commonly used platinum agents, cisplatin or carboplatin, is the best and to find out if cisplatin 80 mg/m<sup>2</sup> is better than 50 mg/m<sup>2</sup> in combination with gemcitabine.

## Treatments and potential benefits

### Examination

You will be given a complete physical examination and your medical history will be taken. Scans using X-rays will be done to look at your disease status. Blood samples (approximately 40mls or 2 tablespoons per visit) will be taken and if you are a woman of childbearing potential, a pregnancy test will be done.

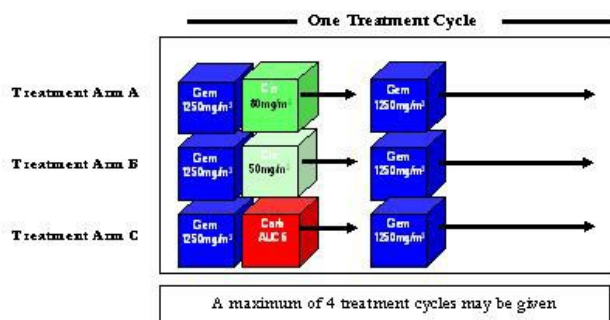
### Consent

Once you have signed the consent document and the tests outlined above indicate it is safe for you to have the study chemotherapy, you will begin the treatment you have been allocated. Treatment consists of the chemotherapy drugs given through a drip into your vein on the 1st and 8th day of a 21-day treatment cycle. Up to 4 treatment cycles may be given.

### Dosage calculation

The dose of gemcitabine and cisplatin are dependent on your height and weight that are used to calculate your body surface area (m<sup>2</sup>). The greater your body surface area the more milligrams of drug are required. However in the case of carboplatin, dose used is dependent on kidney function. This is because carboplatin is removed from your body principally by your kidneys; the better your kidneys work the higher the dose of carboplatin needed.

Tests & Procedures	Before Treatment Starts	Cycle 1 (Day 1)	Cycle 1 (Day 8)	Cycle 2-4 (Day 1)	Cycle 2-4 (Day 8)	End of Treatment (Between 4 & 6 weeks after start of last cycle)	Follow Up each Month x 6
Read information. Sign Consent	✓						
Physical Examination	✓			✓		✓	✓
Medical History	✓						
Blood Tests	✓			✓			
Other Current Medication	✓	✓	✓	✓	✓	✓	✓
Scanning Procedure (Thoracic CT Scan)	✓			✓ (Cycle 2 Only)		✓	✓
Scanning Procedure Chest X-Ray	✓			✓		✓	✓
Toxicity Assessment			✓	✓	✓	✓	✓
Quality of Life	✓			✓		✓	✓



### Day One

On Day One of each treatment cycle you will receive the chemotherapy drug Gemcitabine, (1250mg/m<sup>2</sup>) administered through a drip for approximately 30 mins.

You will then be given one of the following treatments you have been randomised to receive:- Cisplatin at 50 mg/m<sup>2</sup> OR Cisplatin at 80 mg/m<sup>2</sup> OR Carboplatin AUC 6 Administered through a drip for approximately one hour.

**NOTE:** If you receive cisplatin you will also receive extra fluids through the drip to help protect your kidneys from damage from the drug. Therefore the total time spent receiving cisplatin-based treatment is expected to be 6 hours and total time spent receiving carboplatin-based treatment is expected to be 1.5 hours.

### Day Eight

On Day Eight of each treatment cycle you will receive the gemcitabine treatment only, again administered through a drip for approximately 30 mins.

### Before each chemotherapy dose

Before each chemotherapy dose you will have a physical examination. You will be asked about any medical problems or changes in medication since the previous visit. Blood samples will be taken to see how the drugs are affecting you and to make sure it is still safe to continue to treat you. Also scans using X-rays will be taken to look at your disease status before treatment cycles 2, 3 and 4 begin.

### End of treatment

At the end of the full treatment you will also have a physical exam, blood tests, and you will be asked about any medication changes or medical problems that you may have had during the previous month and a scan using X-rays will be taken, to look at your disease status. Any side effects continuing at that time will be followed until they

have resolved or stabilized.

You will then be asked to return to clinic every 4 weeks up to a period of 6 months to find out if you have had any medical problems during the previous month. At these visits the doctor will perform a physical examination and a chest X-ray will be taken.

## Side effects

As with all medicines of this type there may be some unwanted side effects. You should discuss these with your doctor. The more common side-effects are listed below; there may also be other side effects that we cannot predict.

### Cisplatin

Side effects that are common after treatment with cisplatin include: nausea and vomiting (you will receive tablets to prevent or help control this); effects on nerves, which may cause ringing in the ears and mild deafness (difficulty hearing in a crowded room) or tingling or numbness in the hands and feet, which may result in difficulties with some tasks, such as doing up buttons (these effects on nerves occur in a minority of patients and if they occur, happen near the end of the planned 4 courses of treatment); kidney toxicity (in order to ensure this does not become a major problem for you, your kidney function is checked before every cisplatin treatment); and finally temporary changes in blood test, which may make you more prone to infection and bruising.

### Cartplatin

Side effects that are common after treatment with carboplatin include: nausea and vomiting, (this is less common than with cisplatin and you will receive tablets to help this); fatigue; temporary changes in blood test, which may make you more prone to infection and bruising. This is more common with carboplatin than with cisplatin.

### Gemcitabine

Side effects that are common after treatment with gemcitabine include: mild nausea and vomiting (you will receive tablets to help this); fatigue; flu-like symptoms; skin rash, which can occasionally be quite severe and if it occurs you should contact your research nurse/consultant; and finally temporary changes in blood test which may make you more prone to infection and bruising.

### General

In addition, there may be unknown (or unforeseeable) side effects that may occur. Your doctor will be watching you closely to see what side effects you have and can prescribe treatment to relieve your side effects if you need it.

In addition, caution is necessary with all drugs used to treat cancer during pregnancy. The study drugs, like any anti-cancer drug, are likely to cause harm to the embryo, foetus or infant if administered during pregnancy or while nursing. Therefore, if there is a possibility you could become pregnant during the study, you must agree to practice birth control.

You will be informed of any new significant findings that develop with any of the study treatments that may affect your willingness to continue participation in this study.

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