

# An open randomised study of the efficacy of standard radiotherapy with and without the addition of SRL172 (*Mycobacterium vaccae*) in the treatment of patients with small cell lung cancer (SIRON 13)

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr - -

**Contact details**  
UKCCCR Register Co-ordinator  
MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

SIRON 13

# Study information

### Scientific Title

An open randomised study of the efficacy of standard radiotherapy with and without the addition of SRL172 (Mycobacterium vaccae) in the treatment of patients with small cell lung cancer (SIRON 13)

### Study objectives

Not provided at time of registration

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied

Lung (small cell)

### Interventions

1. Standard chemotherapy (as per protocol)
2. Standard chemotherapy + SRL172 injections (as per protocol)

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Not provided at time of registration

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/2000

### **Completion date**

31/12/2001

## **Eligibility**

### **Key inclusion criteria**

1. Patients should be aged at least 18 years with histologically and/or cytologically confirmed unresectable small cell lung cancer, which includes limited or extensive stage disease
2. There should be presence of measurable or evaluable disease
3. Patients should be World Health Organisation (WHO) performance status 0-2
4. Serum creatinine <140 micromol/l or creatinine clearance >50 ml/min (if serum creatinine 120-140 micromol/l) if receiving cisplatin. If receiving carboplatin, creatinine clearance >20ml/min
5. Life expectancy >3 months
6. Written informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

### **Target number of participants**

Not provided at time of registration

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/01/2000

### **Date of final enrolment**

31/12/2001

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**UKCCCR Register Co-ordinator**  
London  
United Kingdom  
NW1 2DA

## Sponsor information

**Organisation**  
UK Co-ordinating Committee for Cancer Research (UKCCCR)

**Sponsor details**  
MRC Clinical Trials Unit  
222 Euston Road  
London  
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**Sponsor type**  
Government

**ROR**  
<https://ror.org/054225q67>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer organisations (UK)

## Results and Publications

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2004	26/03/2020	Yes	No