Chapter VIII

Miscellaneous,

CRF and

Master Chart
INFORMED CONSENT

I have read the attached information sheet and have been also explained verbally in detail the purpose and the procedure of the study in vernacular / non-technical language. I can raise further questions at any time and I am assured that these will be answered. I have not been given any inducement and agree to participate in the study of my free will.

I am aware of my responsibilities upon enrolling in the study. I have also been told that I can withdraw from the study at any time without assigning any reason.

I hereby give my consent for the trial entitled, “Clinical evaluation of a unani adjuvant formulation for enhancement of efficacy of anti tubercular treatment”.

Name of the patient

Signature

Signature of Investigator

Date:

Date:

Address:
CASE RECORD FORM

"Clinical Evaluation of a Unani Adjuvant Formulation For Enhancement of Efficacy of Anti Tubercular Treatment"

Name: ... ... .............. Sex...........................................
S.No. ... ... ................ Father Name..........................
Age:..................................... Marital status......................
Occupation........................ Native place:....................... 
Religion.............................. Date of starting the drug........
IDNo/R. No.........................
Group................................ Case No.........................
EXCLUSION CRITERIA

INCLUSION CRITERIA

1. Is the patient a new smear positive case. Yes[ ] No [ ]
2. Is the patient a New case smear negative but culture positive pulmonary tuberculosis Yes[ ] No [ ]
3. Is the patient willing to given informed consent. Yes[ ] No [ ]

IF ANSWER TO ALL THE QUESTIONS IS YES THEN INCLUDE THE PATIENT.

The following patients will be excluded in the study.

1. Is the patient suffering from extrapulmonary or miliary TB Yes[ ] No [ ]
2. Is the patient suffering from peptic ulcer, hepatitis, hepatic or renal insufficiency, malignancy or any cardiovascular disease, fungal infection, HIV, diabetes mellitus. Yes[ ] No [ ]
3. Is the patient pregnant or lactating women Yes[ ] No [ ]
4. Is the patient an alcoholic Yes[ ] No [ ]
5. Is the patient receiving any oral contraceptives Yes[ ] No [ ]
6. Is the patient receiving any antiepileptic drugs Yes[ ] No [ ]

IF THE ANSWER TO ANY OF THE QUESTIONS IS YES, EXCLUDE THE PATIENT

Relevant past history:

........................................................................................................

........................................................................................................
PERSONAL HISTORY

**Occupation**  
Student [ ] Unemployed[ ] Housewife[ ] Employed[ ]

**Diet habits**  
Veg [ ] Non veg [ ]

**Social status:**  
Hygienic [ ] Unhygienic [ ] Overcrowding [ ]

**Addiction:**

*Smoking*  
Yes [ ] No [ ]

if yes, No. of cigarettes / bidis

*Tobacco chewing*  
Yes [ ] No [ ]

*Alcohol*  
Yes [ ] No [ ]

FAMILY HISTORY

Anybody in immediate family has / have tuberculosis

If Yes, who

If Yes, have they been treated

If Yes, duration of treatment, regular / irregular result

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Presenting Chief complain with duration

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes [ ]</th>
<th>No [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evening rise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Night/Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood if any</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appetite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Normal/Slightly reduced/ Markedly reduced)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of weight</td>
<td>(yes/ NO )Duration</td>
<td></td>
</tr>
<tr>
<td>Lethargy</td>
<td>(yes/ No)</td>
<td></td>
</tr>
<tr>
<td>Relevant past history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATT drugs taken, duration &amp; dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have all drugs been taken regularly</td>
<td>Yes [ ]</td>
<td>No [ ]</td>
</tr>
<tr>
<td>If no then number of days not taken in past month</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
If no has it been irregular treatment...

If no which drugs have been taken regularly...

Was cost of medicine the factor...

Was non availability of medicines the reason...

Was pt. Not taking drugs as he was feeling better...

Was patient forgetting to take the drugs...

Did patient stop due to side effects...

**Examination**

General apparence......... Built

Pulse....................... Cyanosis.

BP........................ Oedema (Local/General).

Respiration Rate........... Body weight.

Temperature............... Jaundice.

Lymphadenopathy.........

**Respiratory system:**

Resonance................ Dullness.

Bronchial breathing....... Wheeze.

Crepitations............... Rhonchi.......................... Pleural

rub.........................

**Abdominal examination:** Any significant complain or finding.

Liver........................

Spleen........................

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Any other.

Central nervous system examination: Any significant complain or finding.

Urinary system examination: Any significant complain or finding.

CVS: Any significant complain or finding.

Any Drugs Allergy

Groups

(A) Test group: Test drug (UNIM-104) With ATT

(B) Control group: Placebo (UNIM-104) with ATT
Radiological Assessment (Chest X-ray PA-View)

<table>
<thead>
<tr>
<th>Day 0</th>
<th>End of 2nd month</th>
<th>End of 3rd month</th>
</tr>
</thead>
</table>


Microbiological Assessment

*Sputum Smear for AFB* Positive/Negative

Quantitation: 0; (±/− repeat); 1 + ; 2 + ; 3 + ; 4 +

<table>
<thead>
<tr>
<th>Day</th>
<th>15 Days</th>
<th>1 Month</th>
<th>End of 2nd Month</th>
<th>*End of 3rd Month</th>
</tr>
</thead>
</table>

*Applicable to patients who are smear positive at the end of the 2nd month.
Sputum culture and sensitivity

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Day 0</th>
<th>End of 3rd month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment date wise of testing/sampling</td>
<td>(specify date)</td>
<td></td>
</tr>
</tbody>
</table>

**Culture**
- Sterile after 8 weeks of incubation
- Contaminated after
- *Mycobacterium tuberculosis* isolated
- *Mycobacterium other than tuberculosis* (MOTT) bacilli isolated

**Sensitivity**
1. Sensitive;  
2. Resistant to
   - INH - 0.2 ug/ml  
   - INH - 1 ug/ml  
   - RIF - 1 ug/ml  
   - RIF - 5 ug/ml
### Laboratory Parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Day 0</th>
<th>End of 2&lt;sup&gt;nd&lt;/sup&gt; Month</th>
<th>End of 3&lt;sup&gt;rd&lt;/sup&gt; Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Haemogram</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLC</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>DLC</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ESR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Liver function test</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SGOT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SGPT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.Bilirubin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.Proteins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Kidney function test</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KFT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Urea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.Creatinine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine examination</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Assessment of temperament

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Sanguine</th>
<th>Phlegmatic</th>
<th>Bilious</th>
<th>Melancholic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex</td>
<td>Rudy [Radish]</td>
<td>Chalky Whitish</td>
<td>Pale Yellow</td>
<td>Purple</td>
</tr>
<tr>
<td>Built</td>
<td>Muscular, broad</td>
<td>Fatty &amp; broad</td>
<td>Muscular &amp; thin</td>
<td>Skeletal</td>
</tr>
<tr>
<td>Touch</td>
<td>Hot &amp; Soft</td>
<td>Cold &amp; Soft</td>
<td>Hot &amp; Dry</td>
<td>Cold &amp; Dry</td>
</tr>
<tr>
<td>Hair</td>
<td>Black lustrous, thick rapid growth</td>
<td>Black thin slow growth</td>
<td>Brown thin rapid growth</td>
<td>Brown thin slow growth</td>
</tr>
<tr>
<td>Movement</td>
<td>Active</td>
<td>Dull</td>
<td>Hyperactive</td>
<td>Less active</td>
</tr>
<tr>
<td>Diet</td>
<td>Cold / Dry</td>
<td>Hot / Dry</td>
<td>Cold, moist</td>
<td>Hot / moist</td>
</tr>
<tr>
<td>Weather</td>
<td>Spring</td>
<td>Summer</td>
<td>Winter</td>
<td>Autumn</td>
</tr>
<tr>
<td>Sleep</td>
<td>Normal [6-8 hrs]</td>
<td>In excess</td>
<td>In adequate</td>
<td>Insomnia</td>
</tr>
<tr>
<td>Pulse</td>
<td>Normal [70-80]</td>
<td>Slow [60-70]</td>
<td>Rapid [80-100]</td>
<td>Slow [60-70]</td>
</tr>
<tr>
<td>Emotions</td>
<td>Normal</td>
<td>Clam / Quite</td>
<td>Angry</td>
<td>Nervous</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Temperament of Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damvi [ ]</td>
</tr>
<tr>
<td>Safravi [ ]</td>
</tr>
<tr>
<td>Balghami [ ]</td>
</tr>
<tr>
<td>Sodavi [ ]</td>
</tr>
</tbody>
</table>

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### Clinical Parameters (Clinical assessment by the doctor)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Basal</th>
<th>After 15 days</th>
<th>After 30 days</th>
<th>After 45 days</th>
<th>After 60 days</th>
<th>After 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum**</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fever***</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Appetite****</td>
<td></td>
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</tr>
<tr>
<td>Haemoptysis*****</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Nightsweat******</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

* (1) No cough, (2) Mild cough, (3) Moderate cough, (4) Severe cough

**(1) No, (2) Yes

*** (1) 97-99.6 °F, (2) 99.7-100.6 °F, (3) 100.7 - > 102 °F

**** (1) Normal, (2) Mild loss, (3) Moderate, (4) Severe

***** (1) No, (2) Yes

****** (1) No, (2) Yes

**Global tolerance: As reported by patient**

1. Very good
2. Good
3. Fair
4. Nil
Global tolerance: As reported by physician

1. Very good
2. Good
3. Fair
4. Nil

Global efficacy: As reported by patient

1. Much better
2. Better
3. Little better
4. No improvement
5. Worse

Global efficacy: As reported by physician

1. Much better
2. Better
3. Little better
4. No improvement
5. Worse

Adverse effect of the test drug if any:

Gastro intestinal Tract

Nausea □ Vomiting □ Abdominal pain □ Diarrhea □

Dermatological

Skin rashes □ Itching □

Any others Adverse effect :

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
Adverse reaction of anti tubercular drugs:

**Rifampicin:**
- Nausea □
- Vomiting □
- Skin Rashes □
- Peripheral neuropathy □
- Liver impairment □
- Anorexia □
- CNS Disturbance □

**Isoniazid:**
- Peripheral neuropathy □
- Anemia □
- Pellagra □
- Mental disturbance □
- Convulsion □
- Incoordination □
- Rashes □
- Weakness □

**Pyrazinamide:**
- Anorexia □
- Nausea □
- Vomiting □
- Dysuria □
- Elevation plasma uric acid □

**Ethambutol:**
- Eye pain blurred vision □
- Retro-bulbar neuritis □
- Numbness □
- Nausea □
- Vomiting □

**Drop out:**
- Yes [ ]
- No [ ]

If yes, reason

(a) No response
(b) Adverse event
(c) Any other reason

Follow up after three month of completion of test drug therapy, any comment.