

Trial No.:

CONFIDENTIAL WHEN COMPLETE

UNIVERSITY OF
BIRMINGHAM



PREGNANCY FORM

IDENTIFYING DETAILS

Trial No.:

Initials:

Site Name:

Date of appointment: / /

REPORT TYPE

Initial Report ☐

Final Report ☐

Pregnancy Notification (PART 1)

PREGNANCY INFORMATION

Date of last menstrual period: / / Not available ☐

Date pregnancy confirmed: / / Not available ☐

Expected date of delivery: / / Not available ☐

TRIAL INTERVENTION SUMMARY

Please indicate if the participant has received any of the trial intervention(s) indicated below. If so, please provide the date of their last dose of carvedilol and/or* the date of the last variceal band ligation procedure:

Trial intervention(s) received <i>Carvedilol and/or variceal band ligation</i>			<i>Last date of last dose (carvedilol) last date of last procedure (variceal band ligation)</i>
	No	Yes	
Carvedilol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Variceal band ligation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

****If participant has received both trial interventions (i.e. in the case of crossover), please state most recent date for both interventions***

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Pregnancy Outcome (PART 2)

Date of pregnancy outcome: / /

What was the outcome of the pregnancy?

No Yes

Induced abortion (no medical indication) ☐ ☐

Induced abortion (medical reason(s)) ☐ ☐

If yes, please specify:

Miscarriage ☐ ☐

Stillbirth ☐ ☐

Livebirth ☐ ☐

If yes, please complete the following questions.

No Yes

Birth defects ☐ ☐

If yes, please specify:

No Yes

Neonatal unit admission ☐ ☐

If yes, please specify:

No Yes

Neonatal death ☐ ☐

If yes, please specify:

Guidance:

Please also report the following events on a CALIBRE SAE Form and send to the CALIBRE Trial Office within 24 hours:

- Induced abortion (medical reason(s))
- Miscarriage
- Stillbirth
- Birth defects
- Neonatal unit admission
- Neonatal death

Comments:

Mother's relevant medical history and other medication taken during pregnancy.

CRF completed by:

You **must** have signed the trial signature and delegation log

Date: / /

Name:

(please print)

Signature: