Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0053	Subject Initials :YND	DOB :04/13/1992	Sex:Female	Race:Asian	Height:155cm	Weight:45.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/14/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	06/05/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
Laparoscopic tubal colostomy, pelvic surgery sticky points.	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0102	Subject Initials :HYD	DOB :10/14/1985	Sex:Female	Race:Asian	Height:163cm	Weight:57.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/19/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/01/2015	06/12/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
Palace laparoscopy	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0118	Subject Initials :MLF	DOB :08/03/1984	Sex:Female	Race:Asian	Height:160cm	Weight:55.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/21/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/07/2015	06/12/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2007	Not on treatment/medication	
Laparoscopic pelvic sticky points, bilateral ovarian drilling	Uk-Unk-2007	Not on treatment/medication	
Cervical biopsy showing inflammation	Uk-Unk-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0136	Subject Initials :Q-L	DOB :03/28/1984	Sex:Female	Race:Asian	Height:154cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/08/2015	06/12/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction incomplete	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0137	Subject Initials :YLF	DOB :11/01/1989	Sex:Female	Race:Asian	Height:153cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/09/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0157	Subject Initials :Y-Z	DOB :07/22/1984	Sex:Female	Race:Asian	Height:156cm	Weight:55.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/25/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/10/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2010	Not on treatment/medication	
Laparoscopic Surgery: Tubal clear.	Uk-Unk-2007	Not on treatment/medication	
Ectopic pregnancy laparoscopic surgery: tubal embryo window.	Uk-Jan-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0161	Subject Initials :H-Y	DOB :12/12/1985	Sex:Female	Race:Asian	Height:166cm	Weight:57.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/26/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/10/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2007	Not on treatment/medication	
Laparoscopic tubal surgery sticking points.	Uk-Unk-2007	Not on treatment/medication	
Open left fallopian tube ectopic pregnancy surgery	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-13 End Date:2016-05-16

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0178	Subject Initials :XSC	DOB :10/11/1988	Sex:Female	Race:Asian	Height:155cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/10/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal resistance.	Uk-Jan-2013	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, bilateral salpingo-repair plastic surgery, normal uterine shape.	Uk-Jan-2013	Not on treatment/medication	
Hysteroscopy normal, water surgery: incomplete right fallopian tube obstruction	Uk-Feb-2015	Not on treatment/medication	