Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0224	Subject Initials :JXL	DOB :11/11/1985	Sex:Female	Race:Asian	Height:158cm	Weight:52.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/01/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/19/2015	09/25/2015		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 occlusion in the left effusion	Uk-Unk-2014	Not on treatment/medication	
Laparoscopic pelvic adhesions dissection and bilateral tubal fluid plastic ostomy, hysteroscopic resection of endometrial polyps palace	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0226	Subject Initials :BQX	DOB :07/10/1987	Sex:Female	Race:Asian	Height:160cm	Weight:53.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/01/2015	187.5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/17/2015	09/22/2015		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 surgery classification pelvic adhesions, tubal fluid prosthetics	Uk-Unk-2010	Not on treatment/medication	
Laparoscopic surgery classification pelvic adhesions, tubal fluid prosthetics	Uk-Unk-2011	Not on treatment/medication	

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Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0227	Subject Initials :YXZ	DOB :12/09/1985	Sex:Female	Race:Asian	Height:164cm	Weight:56.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/01/2015	187.5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/17/2015	09/22/2015		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
Abdominal ectopic pregnancy conservative surgery.	Uk-Unk-2012	Not on treatment/medication	
Ectopic pregnancy laparoscopic conservative surgery.	Uk-Unk-2013	Not on treatment/medication	
HSG: incomplete right fallopian tube obstruction, left fallopian tube fluid.	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0228	Subject Initials :J-X	DOB :09/12/1981	Sex:Female	Race:Asian	Height:160cm	Weight:51.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/02/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/20/2015	09/25/2015		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: right fallopian tube obstruction.	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0229	Subject Initials :HYT	DOB :11/13/1992	Sex:Female	Race:Asian	Height:153cm	Weight:45.5kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/02/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/18/2015	09/24/2015		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 occlusion	Uk-Unk-2013	Not on treatment/medication	
Laparoscopic surgery: pelvic adhesions dissection, tubal plasty, uterine fibroids dug surgery, uterine suspension surgery.	Uk-Unk-2013	Not on treatment/medication	
Hysteroscopy normal	Uk-Unk-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0230	Subject Initials :F-X	DOB :07/08/1987	Sex:Female	Race:Asian	Height:156cm	Weight:51.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/02/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/18/2015	09/24/2015		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
Caesarean section	Uk-Unk-2009	Not on treatment/medication	
HSG: bilateral tubal occlusion	Uk-Mar-2015	Not on treatment/medication	
Hysteroscopy normal	Uk-Unk-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-12 End Date:2016-04-13

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0231	Subject Initials :LJS	DOB :08/28/1981	Sex:Female	Race:Asian	Height:160cm	Weight:69.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	09/02/2015	300	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/17/2015	09/24/2015		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: the left fallopian tube passable	Uk-Unk-2013	Not on treatment/medication	
Palace laparoscopy	Uk-Unk-2014	Not on treatment/medication	