

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0043	Subject Initials :F-H	DOB :03/13/1983	Sex:Female	Race:Asian	Height:164cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/13/2015	225				
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 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			
Laparoscopic tubal ectopic pregnancy at the right side of the window to take embryo	Uk-Unk-2005	Not on treatment/medication				
Under the right fallopian tube ectopic pregnancy laparoscopic surgery	Uk-Unk-2007	Not on treatment/medication				

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NA/EMR700623-541/C02-0043

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Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0046	Subject Initials :Q-H	DOB :10/07/1985	Sex:Female	Race:Asian	Height:161cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/13/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/28/2015	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 patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

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NA/EMR700623-541/C02-0046

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Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0049	Subject Initials :HPT	DOB :09/16/1980	Sex:Female	Race:Asian	Height:155cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	187.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	06/03/2015		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
Laparoscopic surgery appendicitis				Uk-Unk-2012	Not on treatment/medication	

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Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0052	Subject Initials :YLL	DOB :02/07/1992	Sex:Female	Race:Asian	Height:165cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	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 patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

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Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0138	Subject Initials :TTJ	DOB :06/20/1990	Sex:Female	Race:Asian	Height:150cm	Weight:41.0kg
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	06/06/2015	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
Ectopic pregnancy laparoscopic surgery: the right fallopian tube embryo pelvic sticking points				Uk-Jan-2014	Not on treatment/medication	
Hysteroscopy: endometrial polyps.				Uk-Feb-2015	Not on treatment/medication	

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Start Date:2016-05-16 End Date:2016-05-17

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	

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Start Date:2016-05-16 End Date:2016-05-17

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	

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Start Date:2016-05-16 End Date:2016-05-17

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0179	Subject Initials :HYZ	DOB :05/14/1991	Sex:Female	Race:Asian	Height:158cm	Weight:53.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/27/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/11/2015	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
Ectopic pregnancy laparotomy: the left fallopian tube removal.				Uk-Unk-2009	Not on treatment/medication	
Abdominal ectopic pregnancy conservative surgery.				Uk-Unk-2010	Not on treatment/medication	
Hysteroscopy: endometrial polyp excision.				Uk-Jan-2015	Not on treatment/medication	

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Non Serious Adverse Drug Reactions Report

Start Date:2016-05-16 End Date:2016-05-17

Study :EMR200136_583		Investigator :NA		Country of Investigator :Romania	SiteNo:007	
Subject No :007-0003	Subject Initials :	DOB :04/19/1977	Sex:Female	Race:Caucasian	Height:173(cm)	Weight:60(kg)
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Visit 2 (Month 3)	05/04/2015		9			
Visit 5 (Month12)/Early Termination						
Visit 3 (Month 6)	05/04/2015		9			
Visit 1/ Baseline (Day 1)	05/04/2015		9			
Visit 4 (Month 9)	05/04/2015		9			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
elevated ALT and AST	05/30/2015	10/31/2015		Suspected	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication(Othervalue:)		Not applicable	Concomitant medication	Resolved		
Event description:						
Subject received concomitant medications:Yes						
Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Paracetamol	05/04/2015		07/17/2015	500	mg	PRN
LIV 52	05/30/2015		07/19/2015	3	tb	TID
LIV 52	07/20/2015	Yes	12/12/2015	6	tb	TID
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

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